EPA Registration No. 352-902 Vol. 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: Oct. 11, 2016.

SUBJECT: Science review in support of change in formulation of registered products, 7 % and 15% Lotion formulations, EPA Reg. Nos. 352-902 and 352-903, respectively, containing 7 % and 15 % w/w Refined Oil of *Nepeta cataria* as active ingredient.

Decision Number: 521893
DP Number: 436157
EPA File Symbol Number: 352-902 & 352-903
Chemical Class: Biochemical
PC Code: 004801
CAS Number: 8023-84-5
Active Ingredient Tolerance Exemptions: Non- food
MRID Numbers: 500324-01

FROM: Clara Fuentes, Ph. D. Entomologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Angela Gonzales, Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

DuPont Crop Protection has submitted for review upgraded Product Identity and Composition, and CSF, dated Oct. 04, 2016, to reflect change in product formulation for registered products, 7 % and 15% Lotion formulations (EPA Reg. No. 352-902 and 352-903, respectively).

COMMENTS AND RECOMMENDATIONS

Product Chemistry: Acceptable.

Product Identity and Composition, manufacturing process, and discussion of formation of impurities for 7 % and 15 % Lotion formulations, EPA Reg. No. 352-902 and 352-903, respectively, in MRIDs 470033-01 and 474229-01 has been now upgraded in MRID 500324-01 to reflect change in formulation. Refer to Confidential Appendix for specifications.

Mammalian toxicity: Acceptable.

The formulation amendment is not expected to change the toxicological profile of the formulations. It is acceptable to bridge to toxicity data generated on 15 % Lotion formulation (EPA Reg. No. 352-903) that is being cited in support of registration of 7 % Lotion formulation (EPA Reg. No. 352-902). These data were reviewed and found acceptable per Roger Gardner's review memo dated Oct. 10, 2007.

Table 1. Toxicological profile of 15 % Lotion formulation (EPA Reg. No. 352-903).

Study Type/OCSPP Guideline	LD_{50}/LC_{50}/Results	Toxicity Category	MRID
Acute Oral Toxicity/OCSPP 870.1100	> 5,000 mg/kg	IV	469773-01
Acute Dermal Toxicity/OPPTS 870.1200	> 5,000 mg/kg	IV	469773-02
Acute Inhalation Toxicity/OCSPP 870.1300	Waiver	IV	469773-06
Acute Eye Irritation/OCSPP 870.2400	Minimal effect clearing in 24 hours	IV	469773-03
Acute Dermal Irritation/OCSPP 870.2500	Non- irritating	IV	469773-04
Skin Sensitization/OCSPP 870.2600	Not skin sensitizer	IV	469773-05
Hypersensitivity incidents (non-guideline)	None reported		

The cited toxicity data was reviewed by Roger Gardner's review memo dated Oct. 10, 2007.

Product Performance: **Acceptable**.

The formulation amendment is not expected to affect the efficacy of the products. Therefore, data from efficacy studies in MRIDs 469774-24; 469774-25; 473626-03; 470156-02 shows that complete protection times against mosquitoes averaged approximately 6 hours for 7 % and 15 % Lotion formulations. Mean complete protection times against blackflies averaged approximately 7 hours for 7% and 15% Lotion formulations. Doses applied to subjects for testing efficacy are presented on Table 2. The descriptive statistics associated to protection times are presented in Table 3 and 4.

Table 2. Doses (mg/cm^2) Applied to Test Subjects.

Units	7% Lotion	15% Lotion
mg/cm^2	2.56	2.52
$g/600cm^2$	1.536	1.512
mg/m^2	1792	3780
OPPTS 810.3700 rec. values ($g/600cm^2$)	1.50	1.50

Table 3. Protection times (in minutes) for 7% Lotion formulation on 2 different target pests, mosquitoes and black flies, tested in the field.

Descriptive Statistics	**FL-mosquito**	**ME-mosquito**	**ME-black fly**	**ME-black fly**
N	5	5	5	5
Minimum	270	410	338	139
25%ile	276	413	344	310
Median	282	480	480	480
75%ile	469	480	480	480
Maximum	480	480	480	480
Mean	354	453	425	412
StdDev	105	37	75	152
Std Error	47	17	33	68
Lower 95% CI	224	407	332	222
Upper 95% CI	485	499	518	601
Normality P value	>0.10	>0.10	>0.10	>0.10
Passed normality test? (α=0.05)	yes	yes	yes	yes
Skewness	0.30	-0.30	-0.30	-1.1
Kurtosis	-2.2	-2.2	-2.2	-0.92

Table 4. Protection times (in minutes) for 15% Lotion formulation on 2 different target pests, mosquitoes and black flies, tested in the field

Descriptive Statistics	FL-mosquito	ME-mosquito	ME-black fly	ME-black fly
N	10	10	10	10
Minimum	309	480	318	335
25%ile	320	480	418	458
Median	341	480	476	480
75%ile	461	480	480	480
Maximum	480	480	480	480
Mean	374	480	447	461
StdDev	68	0.0	52	46
Std Error	22	0.0	17	15
Lower 95% CI	325	480	409	428
Upper 95% CI	422	480	484	494
Normality P value	>0.10	-	>0.10	0.03
Passed normality test? (α=0.05)	yes	-	yes	no

Mosquito species encountered in Maine and Florida testing sites were identified as: *Culex* complex of spp. *Ochlerotatus intrudens; Psorophora ferox*, *Ochlerotatus atlanticus/tormentor*, *Ochlerotatus taeniorhynchus*, and *Culiseta melanura*; *Culex isolambdis*.

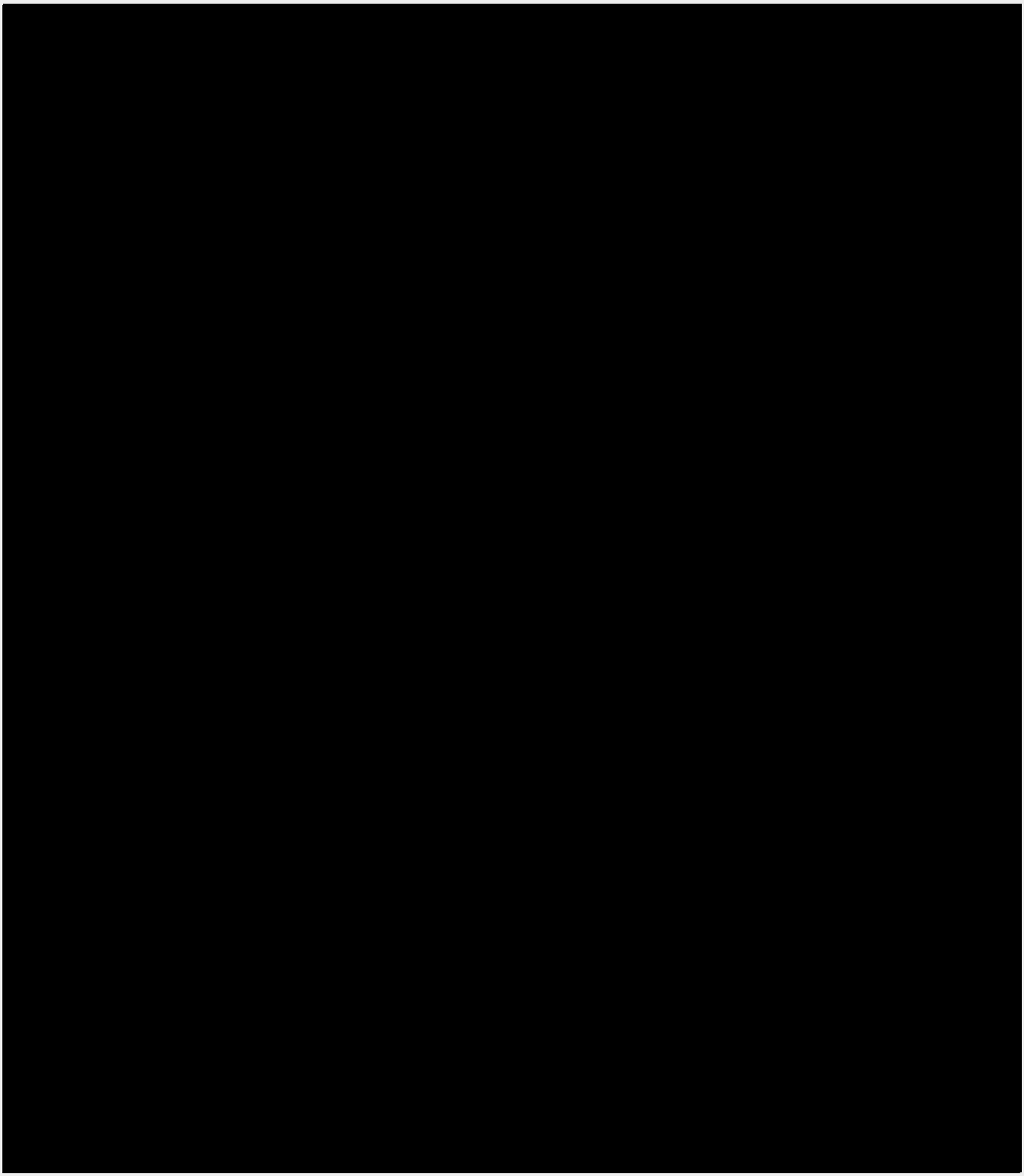
Non-target data:

Risk of exposure to non-target organisms is not expected from the use of these products as insect repellents.

References:

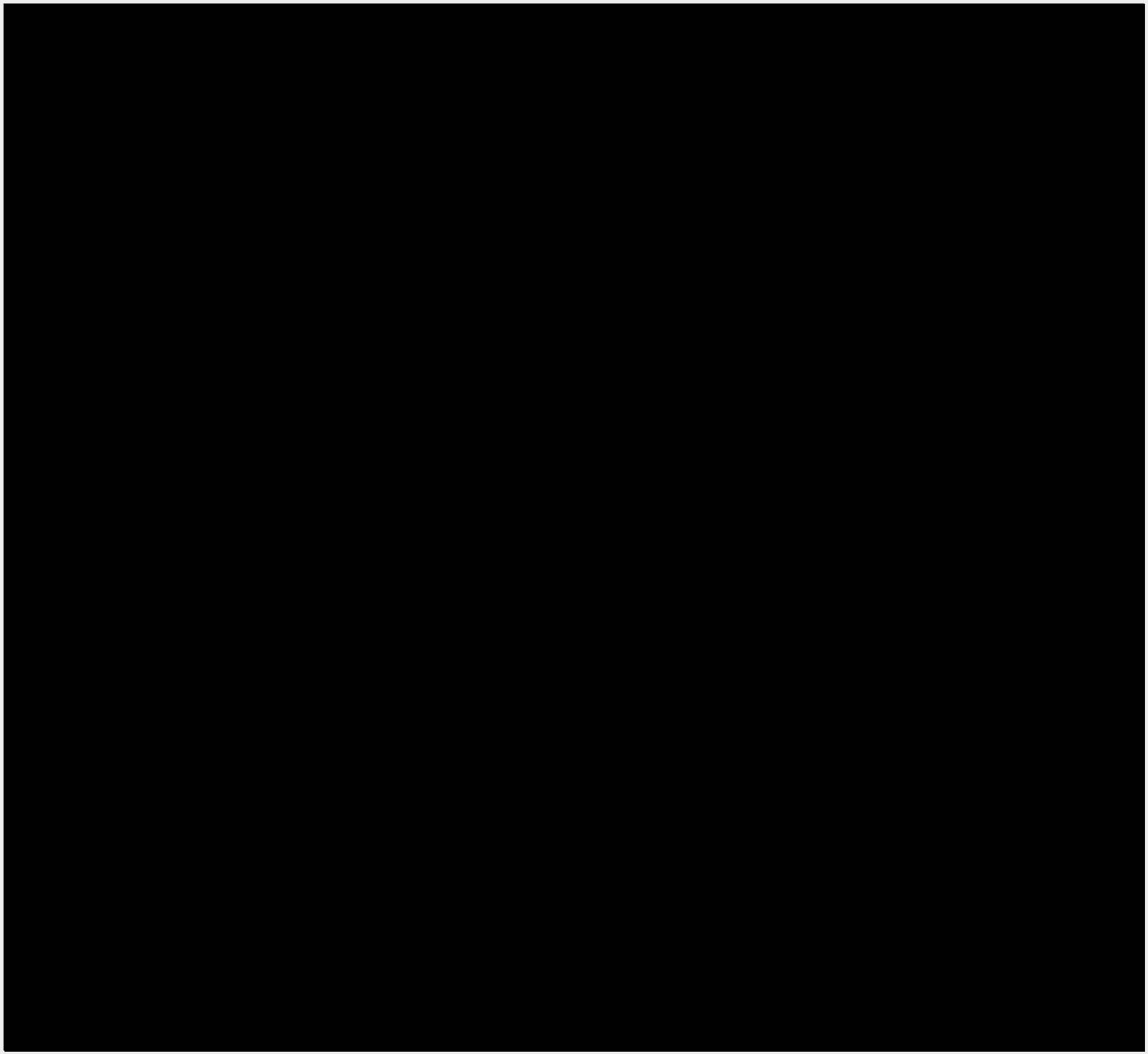
Roger Gardner's review memos of Mammalian toxicity and Human Health Risk Assessment data in MRIDs 469773-01 through 469773-5, dated Oct. 10, 2007.

CONFIDENTIAL APPENDIX



Inert ingredient information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment



CONFIDENTIAL APPENDIX

MRID 500324-01, Manufacturing Process:

[redacted]

Discussion on Formation of Impurities:

No impurities are anticipated during the formulation process.

MSDSs are included from the suppliers of the inert ingredients replacing [redacted].

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 26, 2016

Bonnie J. Bieber
Product Registration Specialist
DuPont Crop Protection
Stine-Haskell Research Center
1090 Elkton Road (S300/431)
Newark, DE 19711

Subject: Pesticide Registration Improvement Act (PRIA) Label and Formulation Amendment – amend the description of formulation process, basic CSF and label to the registration.
Product Name: Refined Oil of *Nepeta cataria* 7% Lotion
EPA Registration Number: 352-902
Application Dates: September 23, 2016 and October 17, 2016
OPP Decision Numbers: 521893 and 522873

Dear Ms. Bieber:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 10/04/2016

Any CSFs other than those listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ms. Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

For

Andrew C. Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 28, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-521893
EPA File Symbol or Registration Number: 352-902
Product Name: REFINED OIL OF NEPETA CATARIA 7% LOTION
EPA Receipt Date: 26-Sep-2016
EPA Company Number: 352
Company Name: E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)

BONNIE J. BIEBER
E. I. DU PONT DE NEMOURS AND COMPANY
DUPONT CROP PROTECTION - STINE-HASKELL RESEARCH CENTER
PO BOX 30
NEWARK, DE 19714-0030

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B680

AMENDMENT;MICROBIAL/BIOCHEMICAL;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO NEW USE(S);NO CHANGE TO AN ESTABLISHED TOLERANCE OR TOLERANCE EXEMPTION;REQUIRES DATA SUBMISSION;REDUCE FEE: ASSOCIATED WITH ANOTHER PRIA ACTION;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-1259.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service {9925178~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 91

Receipt No. S-	992517
EPA File Symbol/Reg. No.	352-902
Pin-Punch Date:	9/26/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B680.0

Granted: B680.1

Amount Due: $ _____

Parent/Child Decisions:

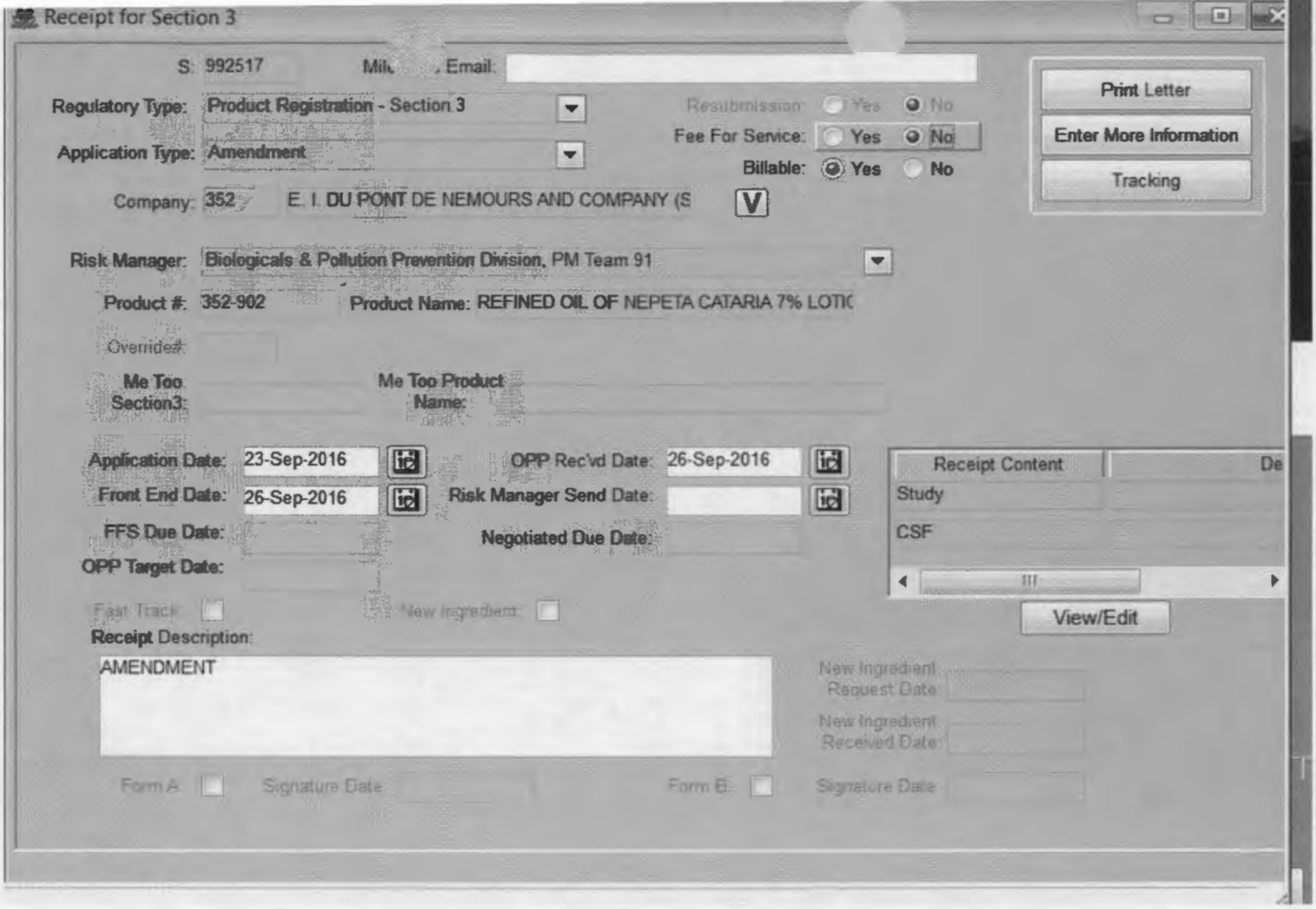
Primary: 352-903

Secondary: 352-902

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Andrew Bayceland Date: 9/27/16

Remarks:


Receipt for Section 3
S: 992517
Email:
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Company: 352 E. I. DU PONT DE NEMOURS AND COMPANY (S
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 352-902
Product Name: REFINED OIL OF NEPETA CATARIA 7% LOTI
Override#
Me Too Section3:
Me Too Product Name:
Application Date: 23-Sep-2016
OPP Rec'vd Date: 26-Sep-2016
Front End Date: 26-Sep-2016
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
De
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
AMENDMENT
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date
Form B:
Signature Date

Pay.gov

Receipt

Your payment is complete

Pay.gov Tracking ID: 25U594VO
Agency Tracking ID: 75100595620
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: $1,277.00
Transaction Date: 09/28/2016 01:08:39 PM EDT
Payment Date: 09/28/2016
Registration Number: 352-902
Company Name: E.I.du Pont de NemoursCo
Company Number: 352
Action Code: B680.1

Account Information

Cardholder Name: Bonnie Bieber
Card Type: Master Card
Card Number: **********2011

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
bonnie.j.bieber@dupont.com

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
352-902	Linda Hollis	☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Refined Oil of Nepeta Cataria 15% Lotion		

5. Name and Address of Applicant *(Include ZIP Code)*

DuPont Crop Protection
Stine-Haskell Research Center,
1190 Elkton Road, Newark, DE 19711 ATTN: B. Bieber

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a Revised Description of Formulation Process and amended CSF for Refined Oil of Nepeta Cataria 15% Lotion (EPA Reg # 352-902)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Bonnie J. Bieber	Product Registration Specialist	(302) 451-4525

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Product Registration Specialist	Bonnie J. Bieber	23-September-2016

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DuPont Crop Protection
Stine Haskell Research Center
P. O. Box 30
Newark, DE 19714-0030

DUPONT

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION: Submission of Amended CSF and Revised Description of Formulation Process

FEE CATEGORY: B680 **REGISTRATION FEE: $5,107**

September 23, 2016

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

SUBJECT: Submission of Revised Description of Formulation Process and Amended CSF's for:

EPA Registration Number	Product Name
352-903	Refined Oil of Nepeta Cataria 7% Lotion
352-902	Refined Oil of Nepeta Cataria 15% Lotion

Dear Ms. Hollis

Amended Confidential Statements of Formula (CSFs) for the two subject products are enclosed. The purpose for submission of these amended CSFs is to replace one of the inert ingredients present in both formulations [redacted]) with substitute inert ingredients that are listed on EPA's list of approved inert ingredients. This substitution plan was discussed with BPPD staff (Linda Hollis, et al.) in a meeting on September 14, 2016.

As presented in that meeting, [redacted] will be replaced with the following inert ingredients:

[redacted]

Inert ingredient information may be entitled to confidential treatment

Taken together, these substitute ingredients are:

- Chemically equivalent to [redacted]
- Serve the same purpose in the formulations
- Present at the same concentration (combined) as [redacted]

In addition to the substitution described above, the following non-substantive changes are being made to both CSFs to update the information and correct minor errors on the current CSFs.

Those changes are:

1. For the TGAI (Refined Oil of *Nepeta cataria*) – Update of the CAS No. to 952722-18-8. This is the CAS No. listed in the Biopesticides Registration Action Document for the TGAI, dated August 25, 2010.

2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

Also being submitted is a revised description of the formulation process for the subject formulations. This revised document updates the list of formulation ingredients and the description of the formulation process to be consistent with the amended CSFs, which are enclosed.

Enclosed in support of this submission are three copies of the report titled "Refined Oil of Nepeta Cataria: Identity and Composition of 15% Lotion and 7% Lotion – Revision to original report identified as MRID 4700330" (identified as DuPont-47695), Form 8570-1, a data transmittal document, one copy of the existing CSF's for each of these formulations, and two copies of the proposed CSF's for each formulation, one with changes highlighted.

Please contact me at (302) 451-4525 or by email bonnie.j.bieber@dupont.com if you have any questions or need additional information regarding the requested action.

Sincerely,

Bonnie J Bieber
Product Registration Specialist
DuPont Crop Protection

DATA TRANSMITTAL DOCUMENT

Refined Oil of *Nepeta cataria*

Name and Address of Submitter:

E.I. DuPont de Nemours and Company
1090 Elkton Road
P.O. Box 30
Newark, DE 19711

Phone (302) 451-4525

Regulatory Action in Support of Which this Package is Submitted:

Information submitted in support of continued registration.

Product Name	EPA Registration No
Refined Oil of Nepeta cataria	352-901
Refined Oil of Nepeta cataria 7% Lotion	352-903
Refined Oil of Nepeta cataria 15% Lotion	352-902

Transmittal Date: September 23, 2016, 2016

List of Submitted Studies:

Data Requirement	Doc Number	Study Title	MRID
880.1100 880.1200 880.1400	.DuPont-47695	Refined Oil of Nepeta Cataria: Identity and Composition of 15% Lotion and 7% Lotion – Revision to original report identified as MRID 47003301	

Submitter: _____ **Date:** 23-Sept-2016

Bonnie J Bieber

Product Registration Specialist

Company Name: E.I. du Pont de Nemours and Company

Company Contact: Bonnie J Bieber

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 10-17-16

Document Part Of: 352-902
MRID, If Any: 500324

Content Screen: Recommended to Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

ANDREW BRYCELAND

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	

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Data Matrix

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Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
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			352	Own	
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			352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
[redacted]			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	
			352	Own	

Signature 	Name and Title: Bonnie J Bieber Registration Specialist	Date: 23-SEP-2016

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1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
DuPont Crop Protection, 1090 Elkton Rd, Newark, Delaware 19714-0030 , 302-451-4525	352-903
Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta cataria	Date 10-4-16
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Outdoor	Product Name Refined Oil of Nepeta Cataria 15% Lotion

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	04-Oct-2016	Bonnie J. Bieber, Registration Specialist

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
830.1700	Solubility Analysis, and Storage Stability Analysis of Hydrogenated Catnip Oil (HCO) Active Ingredient : Report No.P0002395	47003102	352	Own	
830.1800	Enforcement Analytical Method for the Active Ingredient: (Hydrogenated Catnip Oil).: Report No.P0002366	47003103	352	Own	
880.1100	Supplement to Product Chemistry Requirements: (Refined Oil of Nepeta cataria).: Report No.NA	47422901	352	Own	
830.6302, 830.6303, 830.6304, 830.6313, 830.6315, 830.6317, 830.6319, 830.6320, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7840, 830.7950	Summary of Physical and Chemical Characteristics of Technical Grade Active Ingredient: (Refined Oil of Nepeta cataria).: Report No.NA	46977422	352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
830.6302, 830.6303, 830.6304, 830.6315, 830.7000, 830.7100	Physical and Chemical Characteristics of Hydrogenated Catmint Oil TGAI: Color, Physical State, Odor, Flammability, pH and Viscosity: Final Report.: Report No.3280-17	46977420	352	Own	
880.1100, 880.1200	Product Identity and Composition (Refined Oil of Nepeta cataria): Report No.NA	47003101	352	Own	
830.1750	Certified Limits and Supplement to Preliminary Analysis: Report No.NA	47003104	352	Own	
830.6303, 830.6315, 830.7000, 830.7100, 830.7300	Physical and Chemical Characteristics of Refined Oil of Nepeta cataria 15% (w/w) Liquid Formulation 16307048: Physical State, Flammability, pH, Viscosity and Relative Density.: Report No.NA	47181308	352	Own	
880.1100, 880.1200	Identity and Composition of 15% Refined Oil of Nepeta cataria Liquid Formulation.: Report No.NA	47181307	352	Own	
830.1750	Certified Limits: 1630704A Liquid and 1630704B Liquid.: Report No.NA	47181309	352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
830.6303, 830.6315, 830.6317, 830.6320, 830.7000, 830.7100, 830.7300	Summary of Physical and Chemical Characteristics of Formulations CU 1630704A and CU 1630704A: Report No.NA	47181310	352	Own	
880.1100, 880.1200	Identity and Composition of 1630704A Liquid and 1630704B Liquid.: Report No.NA	47425401	352	Own	
830.1800, 830.6313, 830.7840	Analytical Method for Formulations: Refined Oil of Nepeta cataria 15% Lotion: Report No.NA	47003302	352	Own	
830.6302, 830.6315, 830.7000	Physical and Chemical Characteristics of 15 wt.% Hydrogenated Catmint Oil Lotion: Physical State, Flammability and pH: Report No.3280-14	46977311	352	Own	
830.1750	Certified Limits Lotion Formulation CLI 1630802C and CLI 1630802D.: Report No.NA	47003303	352	Own	
830.6302, 830.6315, 830.7000, 830.7100, 830.7300	Summary of Physical and Chemical Characteristics of Formulations CU 1630802C and CU 1630802D.: Report No.NA	46977310	352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
830.7100, 830.7220, 830.7950	Determination of Boiling Point and Vapor Pressure (Static Method) for a Liquid TGAI and Viscosity for Two Lotion Formulations: Report No.DuPont-P00011	47003105	352	Own	
880.1100, 880.1200	Identity and Composition of Formulations CU 1630802C and CU 1630802D.: Report No.NA	47003301	352	Own	
830.6303, 830.6315, 830.7000, 830.7100, 830.7300	Physical and Chemical Characteristics of Refined Oil of Nepeta cataria 7% (w/w) Liquid Formulation 1630704A: Physical State, Flammability, pH, Viscosity, Relative Density: Report No.3280-32	47181402	352	Own	
880.1100, 880.1200	Identity and Composition of 7% Refined Oil of Nepeta cataria Liquid Formulation.: Report No.NA	47181401	352	Own	
830.6303, 830.6315, 830.7000, 830.7100, 830.7300	Physical and Chemical Characteristics of 7 wt Percent Hydrogenated Catmint Oil Lotion: : Physical State, Flammability, and pH, Nepeta cataria Oild: Report No.3280/13	47013901	352	Own	
830.7300	Characterization of Aged Hydrogenated Catnip Oil (HCO) Formulations: Report No.P00009	47234301	352	Own	
830.6317, 830.6320	One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations: Report No.CCAS/200702/SO4	48106201	352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
880.1100, 880.1200, 880.1400	Refined Oil of Nepeta Cataria: Identity and Composition of 15% Lotion and 7% Lotion – Revision to original report identified as MRID 47003301: Report No.DuPont-47695	Submitted Herein	352	Own	
810.3400	Supplement to Efficacy Studies Submitted Under Refined Oil of Nepeta cataria Technical and Manufacturing-Use Product: EPA File Symbol 71654-ER: 1630704A Liquid and 1630704B Liquid: Report No.NA	47181311	352	Own	
NA	Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine.: Report No.0306/313/0141	47015602	352	Own	
NA	Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine.: Report No.0306/313/0141	47113801	352	Own	
NA	Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine: Report No.0306/313/0142	46977424	352	Own	
NA	Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine: Report No.0306/313/0142	47113802	352	Own	
NA	Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida: Report No.0306/313/0143	46977425	352	Own	
NA	Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida: Report No.0306/313/0143	47113803	352	Own	
NA	Response from DuPont to the U.S. EPA Genetic Toxicity Recommendation in 'Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of Nepeta cataria (TGAI), and Two Lotion End-Use Products'.: Report No.NA	47362604	352	Own	

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Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
NA	Supplement: Prediction of Minor Constituents of Refined Oil of Nepeta cataria as Likely Hydrogenation Products.: Report No.NA	47362602	352	Own	
NA	Supplement to Preliminary Analysis: Physical and Chemical Characteristics: (Nepeta cataria oils).: Report No.NA	47370401	352	Own	
NA	Supplement to 'Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Maine' (MRID 46977424), 'Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Florida' (MRID 46977425) : Report No.NA	47362603	352	Own	
NA	Refined Oil of Nepeta cataria:Response to Decision # 434656 (Storage Sstability and Corrosion Characteristics (MRID 48106201)): Report No.DuPont-47312	49993401	352	Own	
870.1100	Hydrogenated Catmint Oil: Acute Dermal Toxicity Study in Rats: Report No.DuPont-17550	46977402	352	Own	
870.1100	Hydrogenated Catmint Oil: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure: Report No.DuPont-17740	46977401	352	Own	
870.1300	Hydrogenated Catmint Oil: Inhalation Median Lethal Concentration (LC50) Study in Rats: Report No.DuPont-17408	46977406	352	Own	
870.2400	Hydrogenated Catmint Oil: Acute Eye Irritation Study in Rabbits: Report No.DuPont-17533	46977403	352	Own	
870.2500	Hydrogenated Catmint Oil: Acute Dermal Irritation Study in Rabbits: Report No.DuPont-17519	46977404	352	Own	
870.2600	Hydrogenated Catmint Oil: Local Lymph Node Assay (LLNA) in Mice: Report No.DuPont-17409	46977405	352	Own	
870.3200	Hydrogenated Catmint Oil: 28-Day Repeated-Dose Dermal Toxicity Study in Rats: Report No.DuPont-17327 RV1	46977415	352	Own	

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Data Matrix

Date: 23-Sep-2016	
Applicant's / Registrant's Name & Address: E. I. DuPont de Nemours and Company, DuPont Crop Protection, P.O. Box 30, Newark, DE 19714-0030	Product: Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
870.3700	Hydrogenated Catmint Oil: Developmental Toxicity Study in Rats: Report No.DuPont-17343	46977408	352	Own	
870.5100	Hydrogenated Catmint Oil: Bacterial Reverse Mutation Test: Report No.DuPont-17471	46977410	352	Own	
870.5300	Hydrogenated Catmint Oil: In Vitro Mammalian Cell Gene Mutation Test (L5178Y/TK+/-Mouse Lymphoma Assay).: Report No.DuPont-17847	46977413	352	Own	
870.5300	Hydrogenated Catmint Oil: In Vitro Kinetics in Rat and Human Skin: Report No.DuPont-19930 RV1	47015601	352	Own	
870.5375	Hydrogenated Catmint Oil: In Vitro Mammalian Chromosome Aberration Study in Human Peripheral Blood Lymphocytes: Final Report: Report No.DuPont-17472	46977411	352	Own	
870.5395	Hydrogenated Catmint Oil: Mouse Bone Marrow Micronucleus Test: Report No.DuPont-18623 RV1	46977412	352	Own	
870.6200	Hydrogenated Catmint Oil: Acute Oral Neurotoxicity Study in Rats: Report No.DuPont-19148	46977409	352	Own	
870.3100, 870.7800	Hydrogenated Catmint Oil: Subchronic Toxicity 90-Day Oral Gavage Study and Immunotoxicity 28- Day Oral Gavage Study in Rats: Report No.DuPont-17324	46977407	352	Own	
870.1100	H-27923: Acute Dermal Toxicity Study in Rats: Report No.DuPont-22750	47181302	352	Own	
870.1100	H-27923: Acute Oral Toxicity Study in Rats - Up- and-Down Procedure: Report No.DuPont-22811	47181301	352	Own	
870.1300	H-27923: Inhalation Median Lethal Concentration (LC50) Study in Rats: Report No.DuPont-21690	47181306	352	Own	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Data Matrix

Date: 23-Sep-2016

Applicant's / Registrant's Name & Address:

E. I. DuPont de Nemours and Company, DuPont Crop Protection,
P.O. Box 30, Newark, DE 19714-0030

Product:

Refined Oil of Nepeta cataria (352-901), Refined Oil of Nepeta cataria 15% Lotion (352-902), Refined Oil of Nepeta cataria 7% Lotion (352-903), Refined Oil of Nepeta cataria 7% Liquid (352-904), Refined Oil of Nepeta cataria 15% Liquid (352-905)

Ingredient: Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study name:	MRID Number	Submitter	Status	Note
870.2400	H-27923: Acute Eye Irritation Study in Rabbits: Report No.DuPont-22812	47181303	352	Own	
870.2500	H-27923: Acute Dermal Irritation Study in Rabbits: Report No.DuPont-22470	47181304	352	Own	
870.2600	H-27923: Local Lymph Node Assay (LLNA) in Mice: Report No.DuPont-21296	47181305	352	Own	
870.1100	Lotion 1630802C: Acute Dermal Toxicity Study in Rats: Report No.DuPont-20889	46977302	352	Own	
870.1100	Lotion 1630802C: Acute Oral Toxicity Study in Rats: Report No.DuPont-20904	46977301	352	Own	
870.1300	Formulation CU 1630802C: Median Lethal Inhalation Concentration Waiver Request.: Report No.NA	46977306	352	Own	
870.2400	Lotion 1630802C: Acute Eye Irritation Study in Rabbits: Report No.	46977303	352	Own	
870.2500	Lotion 1630802C: Acute Dermal Irritation Study in Rabbits: Report No.DuPont-20707	46977304	352	Own	
870.2600	Lotion 1630802C: Local Lymph Node Assay (LLNA) in Mice: Report No.DuPont-20161	46977305	352	Own	

Signature

Name and Title: Bonnie J Bieber
Registration Specialist

Date: 23-SEP-2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 29 APRIL 2009

SUBJECT: Refined Oil of *Nepeta cataria* – Assessment of Toddler Hand-to-Mouth Exposure to Refined Oil of *Nepeta cataria* (Catnip) Applied Dermally as an Insect Repellant.

PC Code:	004801	**DP Barcode:**	D364141
MRID No.:	None	**EPA File Symbol**	71654-EG, -ER
Petition No.:	None	**Regulatory Action:**	Section 3
Assessment Type:	ORE	**Reregistration Case No.:**	None
TXR No.:	None, Number, or See Table	**CAS No.:**	None

FROM: Mark I. Dow, Ph.D., Biologist
Alternate Risk Integration Assessment Team (ARIA)
Risk Integration Minor Use & Emergency Response Branch (RIMUERB)
Registration Division (RD) 7505P

THROUGH: John C. Redden, ARIA Team Leader
RIMUERB/RD 7505P

TO: Raderrio Wilkins, Risk Manager
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division 7511P

INTRODUCTION

Under provisions in Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, the E.I. du Pont de Nemours and Company has requested registration of refined oil of *Nepeta cataria* for use as a dermal topical application as an insect repellant. Two products are proposed: a 7.0 % active ingredient (ai) lotion and a 15.0 % ai lotion.

The Registration Division (RD) has been requested to assess toddler hand-to-mouth exposure that might result from use of the formulation per label directions for use.

The risk assessment techniques used in this document are those that have been developed and refined by the HED/Office of Pesticide Programs' Science Policy Council for Exposure (ExpoSAC). RD herein utilizes the same techniques as are HED's standard operating procedures (SOP).

USE PATTERN SUMMARY

According to draft product labeling for the 7.0 % and 15.0 % lotion formulations, directions for use include: "Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adults [sic] hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands." The label also directs: "Do not apply over cuts or damaged skin." "Do not allow children to handle the product or apply it to themselves."

Label claims include protection from or repellency to "mosquitoes", "black flies", "biting flies" and "a range of biting insects."

DISCUSSION

As noted earlier, the assessment techniques utilized are derived from Health Effects Division (HED) standard procedure. However, there are data utilized herein that are taken from two documents from the Biopesticides and Pollution Prevention Division (BPPD): (1. "BIOPESTICIDES REGISTRATION ACTION DOCUMENT – Refined Oil of *Nepeta casaria* [sic] Hydrogenated Catmint Oil (HCO)" L. Hollis et al., 28 NOV 2008 and 2. Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products", DP Code 338556, 339493, 339547, R. Gardner, 10 OCT 2007).

The refined oil is derived from the plant species *Nepeta cataria* commonly known as catnip. According to Hollis et al. (2008), Refined Oil of *Nepeta cataria* is classified in Acute Toxicity Category III for acute oral toxicity and primary eye irritation and in Acute Toxicity Category IV for acute dermal toxicity, acute inhalation toxicity and skin irritation. It is not a dermal sensitizer.

In Gardner, 2007, a dermal application rate is derived from performance dosimetry studies. The application rate is 0.378 mg active ingredient/cm^2 (of skin). Gardner also identified an acute (incidental) oral toxicological endpoint that is used here to assess toddler oral hand-to-mouth exposure. The endpoint is identified from an acute neurotoxicity study in the rat. The No Observable Adverse Effect Level (NOAEL) is 40 mg/kg. The effects seen were decreased motor activity on the day of dosing in males and females (MRID 45977409).

The risk assessment technique used by RD is modified from the HED "Standard Operating Procedures (SOPs) for Residential Exposure Assessments" 9.2.2

"Postapplication Potential Dose Among Toddlers from Incidental Nondietary Ingestion of Pesticide Residues on Pets from Hand-to-mouth Transfer." (18 DEC 1997). The modification is to account for the label directions which indicate reapplication may be necessary after 6 hours (i.e., 2 treatments/day) and the occurrence of 1 Hand-to-Mouth event/treatment. Thus, the factors used for assessment are:

PDR = (Rate * Dis * SA * FQ * EX * TR)/BW

PDR =	Potential Dose Rate (mg/kg bw/day)
Rate =	Rate of application (0.387 mg ai/cm^2/event)
Dis =	Per cent dislodgeable residue (unitless 5.0) biologically available
SA =	Surface area toddler first 3 digits (20 cm^2)
FQ =	Frequency of Hand to Mouth events (1 Event/treatment)
EX =	Saliva extraction factor (% unitless = 50.0)
TR =	Number treatments (2 treatments/day).

NOAEL = No Observable Adverse Effect Level (40 mg/kg bw/day)
MOE = Margin of Exposure (NOAEL/PDR).

0.378 mg ai/cm^2/treatment * 0.05 (%) * 20 cm^2 * 1 event/treatment * 0.50 (%) * 2 events/day ÷ 15 kg bw = 0.0252 mg/kg bw/day

MOE = NOAEL/ADD thus 40 mg/kg bw/day/0.0252 mg/kg bw/day = 1,587.

CONCLUSIONS

The Agency's level of concern is for Margins of Exposure < 100. Since the estimated MOE is > 100, the proposed use does not exceed the level of concern. The factors used for risk assessment are considered conservative (protective) in terms of the estimated rate of application, estimated amount of available dislodgeable residue and estimated amount of extraction by saliva. Since efficacy data indicate effect times of 6 hours, it is expected that the formulation is not easily removed from the skin's surface.

cc:M.Dow(RIMUERB)
RDI:J. Redden,
M.I.Dow:S7824:PY1:(703)305-5533:RIMUERB:7505P

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: June 30, 2009

SUBJECT: Science Review in Support of the Registration of Refined Oil of *Nepeta cataria* 15% Lotion and Refined Oil of *Nepeta cataria* Lotion 7%, Containing 15% and 7% Refined Oil of *Nepeta cataria* As Its Active Ingredients.

Decision Number:	**371862, 372756** 21
DP Number:	**365995, 365996** 23
EPA File Symbol Number:	**71654-ER, 71654-EG**
Chemical Class:	**Biochemical**
PC Code:	**004801**
CAS Number:	**8023-84-5**
Tolerance Exemptions:	**Non-food Use**
MRID Numbers:	**N/A**

FROM: Jacob Moore, Chemist /s/ 07/07/09 7/7/09
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to the request for additional information relayed in letters from BPPD to the registrant dated 10/17/07 & 4/16/08, the registrant has submitted revised CSF dated 06/12/09 and MSDS for all inert ingredients.

RECOMMENDATIONS AND CONCLUSIONS

1. CSF (06/12/09) is ACCEPTABLE. All inert ingredients are cleared and have appropriate PC Codes.

2. Product chemistry data are ACCEPTABLE. No additional data are required. A year long storage stability study (OPPTS 830.6317) is ongoing and will be submitted upon completion.

Product Chemistry

MSDS were submitted for all inert ingredients contained within the products. In the administrative materials, the registrant notes that a year long storage stability study is in progress and will be submitted upon completion. All other product chemistry data requirements have been successfully addressed.

cc: J. Moore, R. Wilkins, BPPD Science Review File, IHAD/ARS
J. Moore, PT, [illegible]: 07/07/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

APR 16 2008

Re: Application for a Biopesticide Registration
Refine Oil of Nepeta cataria
EPA File Symbol: 71654-ER, EG, EN, EL and EU

Dear Mr. McEntee:

Please refer to my email dated March 13, 2008. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were not cleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a PRIA action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so.
We will therefore need to know, with some urgency how you will proceed. You have the following options:

(A). Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.

(B). Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.

(C). Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of May 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the five products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about May 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response.

Sincerely,

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

OCT 16 2007

Re: Application for a new Biochemical pesticide Registration
Refined Oil of *Nepeta cataria*
EPA File Symbol. No. 71654-EN (100%), 71654-EG (7% Lotion), 71654-ER (15% Lotion)
Your submission of November 30, 2006 and resubmissions of December 19, 2006, December 28, 2006 and January 5, 2007.

Dear Mr. McEntee:

The applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

I. CSF

EPA File Symbol 71654-EN (TGAI):

a. Submit s CAS Registry numbers for all ingredients on the CSF. The must be placed after the component descriptor.

b. All impurities potentially present at >0.1% must be identified individually on the CSF (ie. [redacted], etc?) and have upper certified limits calculated.

c. The information on the top row of the CSF where refined oil of *Nepeta cataria* is identified as "active technical grade" should be deleted.

d. The parentheses around the amounts of the remaining ingredients provided in column 13b of the CSF must be deleted.

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

e. The identity of the active ingredients given on the CSF and the product label must be made consistent.

f. The certified limits are in excess of what is recommended in 40CFR 158.175(b)(2) and ranges determined in preliminary analyses. Please base the certified limits on that presented in the 40 CFR or provide justification for deviations. EPA would like to note that [redacted] EPA considers this range satisfactory for regulatory purposes because the component is undetectable in the final EP products.

g. The lower certified limits for impurities, un-reacted starting materials, etc. must be deleted.

h. The proposed Upper certified limit for [redacted] should be revised to reflect the upper part of the range described in preliminary analyses [redacted] EPA considers this satisfactory for regulatory purposes because the component is undetectable in the final EP products.

i. The proposed upper certified limit for [redacted]). EPA considers these upper limits to be satisfactory, considering the variation present in source material supply, source material composition, the negligible amount of these components in EP products, [redacted]), and the anticipation that no additional toxicity (other than that already associated with dihydronepetalactone) will be associated with these components.

j. Following the addition of other ingredients to the CSF, the please ensure that the percent (%) by weight totals = 100%.

k. Please complete blocks #5. and #6. on the CSF.

EPA File Symbol 71654-EG (7% Lotion)

a. Provide a complete address and CAS registry number for the component [redacted].

b. Please change the CAS No. [redacted] and for [redacted]

c. Please provide a CAS No. for the active ingredient.

d. [redacted] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [redacted]) on the CSF.

f. Please address the discrepancy of why the content of [redacted] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [redacted] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

EPA File Symbol 71654-ER (15% Lotion)

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

II. PRODUCT CHEMISTRY

File Symbol 71654-EG (7% Lotion)

a. Please provide a rationale for the increase in percent weight of [redacted] in the 7% lotion when compared to the TGAI.

b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.

c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

[redacted]

File Symbol 71654-ER (15% Lotion)

a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

III. PHYSCIAL PROPERTIES

EPA File Symbol 71654-EN (TGAI):

a. Please address explodability.

b. Please submit storage stability and corrosion characteristics tests.

c. Please address stability in the presence of different temperatures and metals by discussing the relative impacts that packaging and storage will have on the stability of the product.

d. Please provide a method for the determination of density.

File Symbol 71654-EG (7% Lotion)

a. Please address oxidation/reduction: chemical incompatibility and explodability.

b. Submit storage stability and corrosion characteristics tests upon their completion.

File Symbol 71654-ER (15% Lotion)

a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are **ACCEPTABLE.**

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to

nontarget organisms. EPA will therefore, waive the testing guideline for Tier I non-target toxicity applicable to TGAI.

IV. PRODUCT PERFORMANCE

a. Please provide detailed discussion on the statistics employed to analyze the data.

b. Please address the inconsistencies concerning the amount of test material applied to subjects.

c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).

d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of November 21, 2007 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the three products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 21, 2006. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately or within five (5) days from the date of this letter at (703) 308-1259 with your response.

Sincerely,

Linda Hollis., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: June 30, 2009

SUBJECT: Science Review in Support of the Registration of Refined Oil of *Nepeta cataria* 15% Lotion and Refined Oil of *Nepeta cataria* Lotion 7%, Containing 15% and 7% Refined Oil of *Nepeta cataria* As Its Active Ingredients.

Decision Number:	**371862, 372756**
DP Number:	**365995, 365996**
EPA File Symbol Number:	**71654-ER, 71654-EG**
Chemical Class:	**Biochemical**
PC Code:	**004801**
CAS Number:	**8023-84-5**
Tolerance Exemptions:	**Non-food Use**
MRID Numbers:	**N/A**

FROM: Jacob Moore, Chemist /s/ 07/07/09 7/7/09
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to the request for additional information relayed in letters from BPPD to the registrant dated 10/17/07 & 4/16/08, the registrant has submitted revised CSF dated 06/12/09 and MSDS for all inert ingredients.

RECOMMENDATIONS AND CONCLUSIONS

1. CSF (06/12/09) is ACCEPTABLE. All inert ingredients are cleared and have appropriate PC Codes.

2. Product chemistry data are ACCEPTABLE. No additional data are required. A year long storage stability study (OPPTS 830.6317) is ongoing and will be submitted upon completion.

Product Chemistry

MSDS were submitted for all inert ingredients contained within the products. In the administrative materials, the registrant notes that a year long storage stability study is in progress and will be submitted upon completion. All other product chemistry data requirements have been successfully addressed.

cc: J. Moore, R. Wilkins, BPPD Science Review File, IHAD/ARS
J. Moore, FT, PM-S: 07/07/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 13 2008

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

Re: Application for a new Biochemical pesticide Registration
Refined Oil of *Nepeta cataria*
EPA File Symbol. No.: 71654-EN (TGAI), -EG , -ER,
PRIA Due Date November 30, 2008

Dear Mr. McEntee:

Please refer to my email dated May 28, 2008 and deficiency letter dated April 16, 2008. Your application remains deficient and we can not proceed with reviewing your application for the end use formulations with the inert clearance issue being unresolved. We renegotiated the Pria due dates for your products to reflect a date of November 30, 2008 with the understanding that you would address the "all" of the deficiencies identified in the Agency's letter dated October 16, 2007, along with submitting the materials necessary for the Inerts Branch to review and possibly resolve. BPPD was informed by Karen Angulo and ~~Prakasheha Shah~~ of the Inerts Branch that you have not submitted the requested information in a formal request or petition to have the inerts reviewed for clearance.

Therefore, your applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

I. CSF

EPA File Symbol 71654-EG (7% Lotion)

a. Provide a complete address and CAS registry number for the component [redacted]

b. Please change the CAS No. for [redacted]

c. Please provide a CAS No. for the active ingredient.

d. [redacted] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [redacted] on the CSF.

f. Please address the discrepancy of why the content of [redacted] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [redacted] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

EPA File Symbol 71654-ER (15% Lotion)

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

II. PRODUCT CHEMISTRY

File Symbol 71654-EG (7% Lotion)

a. Please provide a rationale for the increase in percent weight of [redacted] in the 7% lotion when compared to the TGAI.

b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.

c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB – Pv Shah, Shah.Pv@epa.gov).

[redacted]

File Symbol 71654-ER (15% Lotion)

a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

III. PHYSCIAL PROPERTIES

File Symbol 71654-EG (7% Lotion)

a. Please address oxidation/reduction: chemical incompatibility and explodability.

b. Submit storage stability and corrosion characteristics tests upon their completion.

File Symbol 71654-ER (15% Lotion)

a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are **ACCEPTABLE.**

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to nontarget organisms. Please address the data requirements by submitting data or a request to waive the data requirement (the data matrix must reflect this request along with MRIDs and rationale for waiving).

IV. PRODUCT PERFORMANCE

a. Please provide detailed discussion on the statistics employed to analyze the data.

b. Please address the inconsistencies concerning the amount of test material applied to subjects.

c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).

d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there is not enough time remaining before the PRIA decision date of November 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. The deficiencies outlined above for the three end use products in addition to review and clearance of the inert ingredients contained in the proprietary blend will require EPA review and regulatory decision making of 8 months post the date that the information is resubmitted to the Agency.

Therefore, you may renegotiate the due dates for the three products above, or withdraw the applications and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response. Again, we will require an extension time of 8 months post the date that you expect to make a full resubmission of the information. We can not renegotiate the date based on a partial submission. You should allow yourself adequate time for your supplier of the proprietary blend to make the submission (officially) to the Agency in addition to enough time for Dupont to address the above the deficiencies. We must have confirmation of a renegotiated due date from you via email by the close of business on November 20, 2008.

As stated above, the request for clearance of the components in the proprietary blend must be submitted to the Agency from the supplier. The EPA has communicated with your supplier and has indicated what information the Agency will need. Given that this information is confidential, we can tell you that the request must be officially submitted to the Agency to the attention of the Inerts Branch of the Registration Division. The request will be for a petition and must state so. The request or formal submission must petition the Agency for food or non food clearance and must contain the components and amount in the blend. Once received and deemed sufficient, this request for clearance will be scheduled. I strongly suggest that you coordinate the

timing of this submission and the submission which will address the above product chemistry issues. Again, partial submissions will not be considered.

Sincerely,

Linda A. Hollis., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CC:
Pv Shah
Kerry Leifer

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

October 28, 2008

MEMORANDUM

Subject: Inert Ingredient Review of the proposed Confidential Statements of Formula for 71654-EG (12/5/2006) and 71654-ER (10/19/2006)

From: Keri Grinstead
Inert Ingredient Assessment Branch
Registration Division

To: Raderrio Wilkins
Biopesticides and Pollution Prevention Division

The Inert Ingredient Assessment Branch (IIAB) has reviewed the inert ingredients on the proposed Confidential Statements of Formula for the products listed above. Based on this review, IIAB confirms that the following CAS numbers remain not approved for use as inert ingredients in pesticide products: [redacted] Any trade name or proprietary blend products containing these CAS numbers are also not approved for use as inert ingredients. Additionally, the CAS number listed for [redacted] is not valid and the Agency is lacking full compositional information for the following trade name products: [redacted]. Full compositional information for trade name products is necessary for the Agency to verify/review the components for approval.

Some information was received by IIAB for [redacted] however, this information was determined to be insufficient for further IIAB review. The submitter was notified that additional information was necessary and, to date, no further response or information has been received regarding this CAS number. Additionally, IIAB has not received any new inert ingredient requests, petitions, or correspondence regarding the other three CAS numbers [redacted]

Based on this information, the above CAS numbers remain ineligible for use as inert ingredients in pesticide products. For future reference, all inert ingredients on a proposed CSF must be approved for the product's labeled uses prior to the Agency granting a registration.

Information regarding inert ingredients permitted in pesticide products can found on the inerts website at http://www.epa.gov/opprd001/inerts/lists.html. Guidance for submitting a new inert ingredient request/petition and/or submitting compositional information can be obtained by emailing IIAB at InertsBranch@epa.gov or calling Keri Grinstead at 703-308-8373.

Please let me know if I can be of further assistance.

Sincerely,

Keri Grinstead

Keri Grinstead (703)308-8373
Inert Ingredient Assessment Branch
Registration Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

MAY 2 1 2007

DATE: May 21, 2007

SUBJECT: Science Review of Product Performance in Support of the Registration.

Decision Number:	371862
DP Number:	338694
EPA File Symbol Number:	**71654-ER and 71654-EG**
Chemical Class:	Biochemical
PC Code:	**004801**
CAS Number:	**8023-84-5**

Active Ingredient Tolerance Exemptions: No tolerance exemption. Non- food product.
MRID Numbers: 469774-24, 469774-25 and 470156-02

FROM: *Clara Fuentes, Ph. D. Biologist*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

DuPont Chemical Solutions Enterprise requests registration of end-use products, *Refined Oil of Nepeta Cataria 15% Lotion* (EPA Reg. No. 71654-ER), and *Refined Oil of Nepeta Cataria 7 % Lotion* (EPA Reg. No. 71654-EG), containing 15 % w/w and 7 % w/w of new active ingredient, respectively, of hydrogenated catmint oil (also known as refined oil of *Nepeta cataria*). The new products proposed for registration are intended for use as personal skin-applied insect repellents against mosquitoes and black flies. In support of this registration, the registrant has submitted copies of product labels, CSFs and *MRIDs 469774-24, 469774-25, and 470156-02.*

1. Product chemistry data (CSF) are acceptable pending resolution of the deficiencies identified below:

1a. Deficiency #1: The CAS number, [redacted], respectively, are unknown to the Agency.

2. Product Performance data are acceptable pending clarification on the following items:

2a. The study report needs to provide a detailed discussion on the statistics employed to analyze the data.

2b. There is no written study report for these studies, except a brief summary of results and conclusions. The description of the study methods are referenced back to the original protocol. Protocol deviations are not addressed.

2c. The inconsistencies concerning amount of test material applied to subjects need to be resolved (Refer to "Reviewer's comments" at the end of this memo).

2d. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken hourly for 1. This information on landings rate does should appear on the results table (Appendix IV).

2e. The test sites were not monitored for incidence of mosquito-borne diseases prior to testing there. Although this is not a scientific issue, it has ethical implications.

2f. Complete Protection Time can be estimated from landings rather than bites, to minimize subjects' exposure to mosquito bites in the field. It is reported in these studies that the endpoint was bites, and subjects were continuously exposed to mosquitoes throughout the entire duration of the test. Although this approach does not compromise the scientific validity of the data, it has ethical implications.

STUDY SUMMARIES

Product Chemistry

The only product chemistry reviewed herein is the information provided on the CSF dated 4/12/06. No inert ingredient is in list 1. All inert ingredients are in lists 3, 4A, and 4B. None of

the inert ingredients are exempt from the requirement of tolerance. This is a non-food product to be used as insect repellent. The lower and upper certified limits are within acceptable range. The active ingredient statement on the label matches the CSF. pH = 6.09 at 25°C for product 71654-EG, and pH = 5.54 at 25°C. Flash point/flammability > 97°C for both products.

Product Performance

MRDs *469774-24 and 469774-25, and 470156-02*

Introduction

The objective of studies 469774-24 and -25 is to evaluate the efficacy of 4 repellent formulations, containing different concentrations of the same active ingredient, *hydrogenated catmint oil* (CAS #8023-84-5; PC Code: 004801, also known as *Nepeta catia*) against mosquitoes in the field. The test sites were at Nicatous Lodge, Maine, and Collier Seminole State Park, Florida. The type of habitat at these sites are not described in the study reports. The main species of mosquitoes found in Maine was *Ochlerotatus intrudens*. The primary mosquito species found at the Florida site were: *Ochlerotatus atlanticus, O. taenior.hynchus, Psorophora ferox and Culiseta melanura.* Environmental conditions recorded during the studies were within acceptable limits.

The objective of study MRID 470156-02 is to evaluate the efficacy of 4 repellent formulations, containing different concentrations of the same active ingredient, *hydrogenated catmint oil* (CAS #8023-84-5; PC Code: 004801, also known as *Nepeta catia*) against black flies in the field. The test site was at Nicatous Lodge, Maine. The type of habitat at this site was not described in the study report. The main species of black flies found at the study site was *Simulium decorum.* The Environmental conditions recorded during the study were within acceptable limits

Results and Conclusions

MRID 469774-24:

The average number of landings on each control subjects were 14.6 and 17.1 per 5 minutes exposure, ranging from 5 to 43. The average count of landings on whole body suit was 20.4 landings, ranging from 11 to 41 landings. These whole body suit counts were taken hourly during 8 hours of intermittent exposure. (Appendix IV: statistics. Page 66 of 104). The duration of whole body suit's exposure periods are not specified in the report.

The mean CPT for the Lotion (15 % w/w) was 8 hours with no deviations (n=10)
The mean CPT for the Liquid (15 % w/w) was 7.48 hours ± 0.26 (n=10)
The mean CPT for the Lotion (7 % w/w) was 7.33 hours ± 0.33 (n=5)
The mean CPT for the Lotion (7 % w/w) was 4.17 hours ± 1.58 (n=5)

MRID 469774-25:

The average number of landings on each control subjects were 12.1 and 20.4 per 5 minutes exposure, ranging from 5 to 43. The average count of landings on whole body suit was 20.9 landings, ranging from 7 to 49 landings. These whole body suit counts were taken hourly during 8 hours of intermittent exposure. (Appendix IV: statistics. Page 66 of 104). The duration of whole body suit's exposure periods are not specified in the report.

The mean CPT for the Lotion (15 % w/w) was 6.14 hours ± 1.05 (n=10)
The mean CPT for the Liquid (15 % w/w) was 5.14 hours ± 0.22 (n=10)
The mean CPT for the Lotion (7 % w/w) was 5.54 hours ± 1.34 (n=5)
The mean CPT for the Lotion (7 % w/w) was 4.17 hours ± 0.42 (n=5)

MRID 470156-02:

The mean number of landings on each control subjects were 21.7 and 29.6, ranging from 3 to 42 during session 1, and 20.3 and 24.3, ranging from 1 to 56, during session 2. These counts are per 5 minutes exposure. The mean count of landings on whole body suit was 26.3, ranging from 14 to 47 landings during session 1, and 27.2 landings, ranging from 2 to 37, during session 2. These whole body suit counts were taken hourly during 8 hours of intermittent exposure (Appendix IV: statistics. Pg. 99 of 140). The duration of the whole body suit exposure periods are not specified in the report.

Session 1 and 2: Mean CPT for the Lotion (15 % w/w) = 7.31 (±0.56) hours (n=10)
Session 1 and 2: Mean CPT for the Liquid (15 % w/w) = 7.32 (±1.09) hours (n=10)

Session 1 and 2: Mean CPT for the Lotion (7 % w/w) = 6.59 (± 0.26) hours (n= 5)
Session 1 and 2: Mean CPT for the Liquid (7 % w/w) = 5.54 (± 2.28) hours (n=5)

Reviewer Comments:

MRIDs 469774-24 and 469774-25

The repellency of 4 products, 2 lotion and 2 liquid formulations differing in their concentrations of the same active ingredient, were tested in 2 field sites, one site in Maine and another site in Florida. The report does not describe the different habitat characteristics at these 2 test sites. The report provides information on the species, and abundance of mosquito species found at each site. The environmental data shows that the weather was cloudy, humid and on the cold side in Maine (average temperature was high fifties and low sixties ° F); RH was between 80 and 94; and the wind speed was less than 1 MPH. The weather data from Florida shows that it was sunny for the first 4 hours of the test, and then it became cloudy with 100% cloud cover. Raw

data collection sheet indicates that it started raining at the last 2 hours of the test. Apparently, this did not interfere with mosquito activity. The temperature was between 75 and 90 ° F, and RH was between 70 and 96. The wind speed was less than 1 MPH. These environmental conditions are within acceptable limits.

Neither Maine nor the Florida site was monitored for incidence of mosquito borne diseases prior to conducting the study. Site selection was based solely on unobstructed space, abundance and diversity of mosquito species, and mosquitoes' landing rate. All the mosquito species identified at these sites are potential vectors of WNV. While this is not a scientific issue, it has ethical implications.

The informed consent document states that subjects will be treated with less than 1 teaspoon full of formulation, which is the amount that would normally be applied to consumers. This study provides no indication of measuring a typical consumer dose to determine that the amount applied to subjects was the dose normally applied by consumers. The report shows some inconsistencies concerning the amount of test material applied to subjects. On page 7 of 104, it is stated that the lotions will be applied at 0.63 and 0.64 g./ 250 sq. cm skin surface area for the 15% and 7% formulations, respectively. On pages 13 and 16 of 104, the application rate for the 15% lotion is 62g/ 250 sq. cm., and 0.4 g/ 250 sq. cm. for the liquid 15% formulation. However, the report also states that the liquid formulation was applied by volume using a syringe, and the volume will be determined based on the specific gravity of the material. The reported applications for the liquid formulations on page 7 of 104 are given in units of volume, ml., instead of grams as reported on pages 13 and 16.

The whole body count of mosquito landings was taken hourly for unspecified exposure periods throughout the study. The table on page 66 of 104 shows hourly counts and the mean of those landings: 20.9 average landings. It is stated on page 8 of 104, that these counts are per minute. Also on page 8 of 104, it is reported that the landing counts on untreated skin of test subjects are recorded as number of landings per 5 minutes exposure. The information regarding landings rate should be reported on the table.

The endpoint in this study was the First Confirmed Bite, with subjects being continuously exposed to mosquitoes in the field. Frequency of mosquito landings is a good indicator of repellent breakdown. Risk to subjects from continuous exposure to mosquitoes in the field can be minimized by changing the endpoint from bites to landings, and exposing subjects to mosquitoes intermittently for short periods of time.

According to the study protocol, two test substances will be tested simultaneously on separate arms of the same subject. EPA specifically discourages testing more than one product on the same subject, unless the researcher can verify that the proximity of the 2 formulations on the same subject won't compromise the results.

Statistical data analysis is not discussed in any detail. The experimental design could have been analyzed as a 2 X 2 factorial (factors are 2 types of formulation – lotion and liquid - by 2

concentrations of active ingredient), for mean comparison with possible interaction or treatment main effect.

Lastly, the study report only provides a brief summary of the results and conclusion. The report is based entirely on the study protocol as amended. The actual study should be reported as conducted consistently with a copy of the study protocol.

MRID 470156-02

The repellency of 4 products, 2 lotion and 2 liquid formulations differing in their concentrations of the same active ingredient, were tested in 2 field sites, in Maine during 2 separate test sessions. Each test session lasted 8 hours. The report does not describe the different habitat characteristics at these 2 test sites. The predominant black fly species collected at these sites is *Simulium decorum*. The environmental data shows that the weather was sunny at the first day session, and cloudy the second. RH was not recorded the first day session; for the second day session, the RH was between 58 and 88, and the temperature was in the high fifties and seventies ° F. The wind speed was less than 1 MPH. These environmental conditions are within acceptable limits.

The informed consent document states that subjects will be treated with less than 1 teaspoon full of formulation, which is the amount that would normally be applied to consumers. This study provides no indication of measuring a typical consumer dose to determine that the amount applied to subjects was the dose normally applied by consumers. The report shows some inconsistencies concerning the amount of test material applied to subjects. On page 7 of 140, it is stated that the lotion formulations, 15% and 7% w/w of a. i. will be applied at 0.63 and 0.64 g./ 250 sq. cm skin surface area, respectively, and the liquids formulations will be applied as 43 g / 250 sq. cm. On pages 13 and 16 of 140, the application rate for the 15% lotion is 62g/ 250 sq. cm., and 0.4 g/ 250 sq. cm. for the 15 % liquid formulation. However, the report also states that the liquid formulation was applied by volume using a syringe, and the volume will be determined based on the specific gravity of the material. The reported applications for the liquid formulations on page 7 of 140 are given in units of volume, ml., instead of grams as reported on pages 13 and 16.

The endpoint in this study was the First Confirmed Landing, with subjects being continuously exposed to black flies in the field. To evaluate efficacy against black flies, landings will be used instead of bites due to the painful nature of black fly bites.

According to the study protocol, two test substances will be tested simultaneously on separate legs of the same subject. EPA specifically discourages multiple tests on the same subject unless the researcher can verify that the proximity of the 2 formulations on the same subject won't compromise the results.

The protocol, on page 15 of 140, states that if the period of black fly activity were less than 8 hours, subjects would be treated early enough before black fly activity began. The report does

not indicate that subjects were treated well in advance to initiation of the study because the landing rates were considered acceptable over the length of the study period (pg. 10 of 140). There were only 3 exposure periods during the study showing landing rates below 1 landing per minute. This occurred at 2 and 3 hours after test initiation. The conclusion is that if repellency lasted longer than that period, the products would have been effective during those periods as well.

Statistical data analysis is not discussed in any detail. The experimental design could have been analyzed as a 2 X 2 factorial (factors are 2 types of formulation – lotion and liquid - by 2 concentrations of active ingredient), for mean comparison with possible interaction or treatment main effect.

Lastly, the study report only provides a brief summary of the results and conclusion. The report is based entirely on the study protocol as amended. The actual study should be reported as conducted consistently with a copy of the study protocol.

cc: *Reviewer name*, Clara Fuentes
RAL name, Raderrio Wilkins
BPPD Chron File, IHAD/ARS
Date: May 21, 2007

Linda Hollis/DC/USEPA/US
04/20/2007 08:57 AM

To Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>
cc Leonard Cole/DC/USEPA/US@EPA, Raderrio Wilkins/DC/USEPA/US@EPA, Shannon L Koerber <Shannon.L.Koerber@usa.dupont.com>,
bcc
Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of Nepeta cataria; PRIA Date

Dear Mr. McEntee: Your message below to Mr. Raderrio Wilkins suggests that you are unwilling to renegotiate the due date for the above products to our requested date of March2008. Rather, you state that December 21, 2007 is the date acceptable to you. When we met in our offices in March 5th 2007, your packages were still incomplete. As a result of our meeting I forwarded to you the message immediately below: We are unable to accomodate your request of a due date of December21, 2007 and will need to renegotiate to the said date of March 2008. If you are still unwilling to renegotiate to this date then we most likely not be able to complete our reviews by the current date.

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.

2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete's it's review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is accepable in order that we may commence with the paper work for renegotiation.

3. The risk manager who will be assigned to your submissions is Mr. Raderrio Wilkins. As discussed, I encourage you to communicate with Mr. Wilkins with regard to the status of your applications however, please refrain from contacting him until the end of next week to allow him the opportunity to process the application materials as he will not be in receipt of these materials until the end of this week.

I look forward to hearing from you with regerd to the proposed due date and receiving your administrative materials.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)

Linda Hollis/DC/USEPA/US
04/05/2007 01:26 PM

To Thomas.C.McEntee@usa.dupont.com

cc andersen.janet@epa.gov, wilkins.raderrio@epa.gov, cole.leonard@epa.gov, wilkins.raderrio@epa.gov, fuentes.clara@epa.gov

bcc

Subject Catnip Oil Products - The Tech and 2 ep's - Request to Renegotiate

Mr. McEntee: I am writing to you in response to your email to Mr. Raderrio Wilkins of my staff in which you agree to renegotiate the due date for your three pending products from Nov. 17, 2007 to December 21, 2007. The due date of December 21, 2007 is proposed by you based on the fact that you are in disagreement that BPPD will need to negotiate out 3 months from the original due date as communicated to you by me in our meeting of March 1, 2008. We are requesting 3 months of extended time because our records show that the 86-5 deficiencies in addition to deficiencies found during the BPPD preliminary screening and communicated to you in our meeting of March 1st and subsequent email from me to you on March 5th have taken that amount of time for completion. If you recall that during our meeting of March 1st, your submission packages were still deficient. During this meeting and in my follow up email to you where I again described the information necessary to make your packages complete, I stated that the proposed due date will be March 2008 and that there may be the chance that the Agency will complete's it's review prior to that due date. Therefore, our request is to renegotiate the due dates for the above products to March 31, 2008 and I will need for you to confirm, via email, that the proposed new due date is accepable in order that we may commence with the paper work for renegotiation.

An additional new development that may potentially affect the due date is your most recent submission of documents per 1303 which are not 86-5 compliant. We will need to communicate those deficiencies to you (if they have not been already) and allow you the time to correct them. Time added to correct 86-5 deficiencies can have an impact on the PRIA due date.

I apologize if you do not fully understand our process however, it is imperative that we are afforded the time required for each phase of the pria review process so that we are better able to make our regulatory decisions by the dates provided.

I look forward to hearing from you so that we can move this forward.

P.S. As discussed with you in our March 1st meeting, please include or carbon copy me, Linda Hollis, in your communications to John Carley relative to information that you will be submitting.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
03/29/2007 12:29 PM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc Leonard Cole/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA, Shannon L Koerber <Shannon.L.Koerber@usa.dupont.com>

bcc

Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of Nepeta cataria; PRIA Date

Mr. Raderrio Wilkins,

This is to confirm that I have discussed the subject of negotiated PRIA decision date with our management. Because of the time it took to resolve the 86-5 defects, we are agreeable to a PRIA date of December 21, 2007 for 71654-EN and ER. The 71654-EG can be extended although I would expect EPA to reach the same decision as is reached for 71654-ER.

EPA file symbols 71654-EN and 71654-ER were submitted Nov. 1, 2007 and the PRIA fee paid on Nov. 11. Because the confidential appendices were incorrectly paginated per 86-5 there was a delay until mid-December.

You mentioned the front-end screen and a gap associated with the screen. I lack insight into this activity and I'm unable to understand the justification for requesting a three month extension (until March 2008).

Should there be issues with the studies that have been submitted for review, there could be a basis to request an extension in order to respond to the issues. Presently, with the studies in primary review, it is difficult to appreciate that BPPD will not be in a postion to make a decision on these applications by December 2007.

As discussed in the March 1, 2007 meeting with Ms. Linda Hollis, Roger Gardner, Russell Jones and Leonard Cole, the goal is to be able to bring this product to market for the US 2008 summer season. Obtaining the registration in March gives insufficient lead time to address the practical aspects of commercial agreement, supply, state registrations, advertising, logistics and etc. While extending a 12 month process to 15 months is not a large percentage increase, it does have a critical effect on the commercial timing with significant consequences to our business interests. Therefore, I respectfully request that we work together to secure a December 2007 approval.

Thank you for your assistance with our applications for registration.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov
03/05/2007 10:49 AM

To Thomas C McEntee/AE/DuPont@DuPont

cc wilkins.raderrio@epa.gov, cole.leonard@epa.gov

Subject Re: EPA File Symbols 71654-ER, EG

and EN; Refined Oil of Nepeta cataria

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.

2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete's it's review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is accepable in order that we may commence with the paper work for renegotiation.

3. The risk manager who will be assigned to your submissions is Mr. Raderrio Wilkins. As discussed, I encourage you to communicate with Mr. Wilkins with regard to the status of your applications however, please refrain from contacting him until the end of next week to allow him the opportunity to process the application materials as he will not be in receipt of these materials until the end of this week.

I look forward to hearing from you with regard to the proposed due date and receiving your administrative materials.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

02/28/2007 11:01
AM

To
Leonard Cole/DC/USEPA/US@EPA,
Linda Hollis/DC/USEPA/US@EPA

cc

Subject
Confirm Meeting - Thursday March
1, 2007 10:30 am EPA File
Symbols 71654-EG and RE; Refined
Oil of Nepeta cataria lotion

Confirm Meeting - Thursday March 1, 2007 10:30 am- EPA Potomac Yard
Refined Oil of Nepeta cataria
EPA File Symbols 71654-EG (7%Lotion) [23]
ER(15%Lotion) [21]
EN (Technical & manufacturing use) [20]

Mr. Leonard Cole and Ms. Linda Hollis,

This is to confirm the subject meeting. Notes from previous meetings are attached for your reference.

Please let me know if there will be anyone else in attendence besides yourselves.

(See attached file: 20060405 Meeting Notes.doc)(See attached file: 20051207
Meeting Notes.doc)(See attached file: March 17 2005 Meeting Intent Talking
points.doc)(See attached file: EPA DuPOnt Dec 14 2004.doc)

Tom McEntee
302 695 6856
978 335 8055 CELL

Cole.Leonard@epam

ail.epa.gov

To

02/23/2007 09:08 AM

Thomas C McEntee/AE/DuPont@DuPont

cc

David L Hallahan/AE/DuPont@DuPont,

Koerber/AE/DuPont@DuPont,

Shannon L

Yesenia M Pelaez/AE/DuPont@DuPont

Subject

Re: EPA File Symbols 71654-EG and RE; Refined Oil of Nepeta cataria lotion; Ref: telephone Feb 21 2007

Thanks Tom. This is a non-issue. I apologize for creating a stir. After carefully reviewing things and adding thought, I realized that this is a non-food use, and you have provided CAS Reg. Numbers for the inerts. We may have some other minor issues. I'll be in touch with you very soon. I appreciate your patience and understanding.

Leonard Cole

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>

02/22/2007 02:06 PM

To

Leonard Cole/DC/USEPA/US@EPA

cc

Shannon L Koerber <Shannon.L.Koerber@usa.dupont.com>, Yesenia M Pelaez <Yesenia.M.Pelaez@usa.dupont.com>, David L Hallahan <David.L.Hallahan@USA.dupont.com>

Subject

EPA File Symbols 71654-EG and RE; Refined Oil of Nepeta cataria lotion; Ref: telephone Feb 21 2007

Mr. Leonard Cole

Inert ingredient information may be entitled to confidential treatment

Thank you for your telephone call regarding the subject product and details
regarding four of the inerts in the formulation. Please refer to the bookmarked attachments for further documentation of the four ingredients discussed yesterday.

(See attached file: [redacted].pdf)

(See attached file: 20070222 Inerts Complete list.pdf)

[redacted]

Sincerly and thanks for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8066 CELL

transfers of data to third parties.

Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html
(See attached file: [redacted] .pdf)(See attached file: 20070222 Inerts Complete list.pdf)(See attached file: [redacted] (See attached file: [redacted] (See attached file: [redacted] .pdf)(See attached file: 20070222 Inerts Complete list.pdf)(See attached file: [redacted] .pdf)(See attached file: [redacted] .pdf)

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(See attached file: 20060405 Meeting Notes.doc)(See attached file: 20051207 Meeting Notes.doc)(See attached file: March 17 2005 Meeting Intent Talking points.doc)(See attached file: EPA DuPOnt Dec 14 2004.doc)(See attached file: [redacted] .pdf)(See attached file: 20070222 Inerts Complete list.pdf)(See attached file: [redacted] .pdf)(See attached file: [redacted] .pdf)
(See attached file: 20060405 Meeting Notes.doc)(See attached file: 20051207 Meeting Notes.doc)(See attached file: March 17 2005 Meeting Intent Talking points.doc)(See attached file: EPA DuPOnt Dec 14 2004.doc)(See attached file: [redacted] .pdf)(See attached file: 20070222 Inerts Complete list.pdf)(See attached file: [redacted] .pdf)(See attached file: [redacted] .pdf)

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Inert ingredient information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

October 28, 2008

MEMORANDUM

Subject: Inert Ingredient Review of the proposed Confidential Statements of Formula for 71654-EG (12/5/2006) and 71654-ER (10/19/2006)

From: Keri Grinstead
Inert Ingredient Assessment Branch
Registration Division

To: Raderrio Wilkins
Biopesticides and Pollution Prevention Division

The Inert Ingredient Assessment Branch (IIAB) has reviewed the inert ingredients on the proposed Confidential Statements of Formula for the products listed above. Based on this review, IIAB confirms that the following CAS numbers remain not approved for use as inert ingredients in pesticide products: [redacted] Any trade name or proprietary blend products containing these CAS numbers are also not approved for use as inert ingredients. Additionally, the CAS number listed for [redacted] is not valid and the Agency is lacking full compositional information for the following trade name products: [redacted]. Full compositional information for trade name products is necessary for the Agency to verify/review the components for approval.

Some information was received by IIAB for [redacted] however, this information was determined to be insufficient for further IIAB review. The submitter was notified that additional information was necessary and, to date, no further response or information has been received regarding this CAS number. Additionally, IIAB has not received any new inert ingredient requests, petitions, or correspondence regarding the other three CAS numbers [redacted]

Based on this information, the above CAS numbers remain ineligible for use as inert ingredients in pesticide products. For future reference, all inert ingredients on a proposed CSF must be approved for the product's labeled uses prior to the Agency granting a registration.

Information regarding inert ingredients permitted in pesticide products can found on the inerts website at http://www.epa.gov/opprd001/inerts/lists.html. Guidance for submitting a new inert ingredient request/petition and/or submitting compositional information can be obtained by emailing IIAB at InertsBranch@epa.gov or calling Keri Grinstead at 703-308-8373.

Please let me know if I can be of further assistance.

Sincerely,

Keri Grinstead

Keri Grinstead (703)308-8373
Inert Ingredient Assessment Branch
Registration Division

Pages 75-76 - *Inert ingredient information may be entitled to confidential treatment*

71654 - ER and EG
Thomas C McEntee to: Raderrio Wilkins 05/29/2009 04:28 PM

History: This message has been forwarded.

Mr. Raderrio Wilkins,

I am forwarding my e-mail from May 5, 2008, where I had attaced a copy of a response to the earlier chemistry deficiencies. I am also attaching an e-copy of revised CSF's (April 22, 2008)for the product which negate the comments from the chemistry review.

In summary, the CSF used substitute ingredients which are on the EPA list of inerts and have the same functional properties and are chemically substantially similar.

Pleas let me know if these revised CSFs would be acceptable. If you do not find this submission from May 8, 2008 in the files, I will re-submit.

Thank you for your help and have a fine weekend.

(See attached file: 20080422 15% HCO Lotion 8570-4.doc)(See attached file: 20080422 7% HCO Lotion 8570-4 2 pages F .doc)

Tom McEntee
978 312 1136
978 335 8055 CELL
----- Forwarded by Thomas C McEntee/AE/DuPont on 05/29/2009 04:23 PM -----

Thomas C McEntee/AE/DuPont
05/28/2008 10:55 AM

To: Hollis.Linda@epamail.epa.gov@DUPONT_MHUB, Wilkins.Raderrio@epamail.epa.gov
cc:
Subject: Re: Resubmission of Information 71654 - ER and EG (Document link: Thomas C McEntee)

(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf)

Mr. Raderrio Wilkins,

Refer to the cover letter from May 8, 2008 and the added page from EPA DER 9/19/07. Following the November 20067 meeting with you, the formulas were

Inert ingredient information may be entitled to confidential treatment

Re: [redacted]/Approval letter

Elizabeth Fertich to Linda Hollis 03/04/2009 05:03 PM

Cc: Raderrio Wilkins, Pv Shah, Keri Grinstead, Karen Samek

History: This message has been replied to.

Linda,

I looked into your question on the other 3 inert ingredients on your CSF. We received and approved a new nonfood request from [redacted] only. I read over Keri Grinstead's letter from 10/28/2008 and based on discussions with her, there are still outstanding inert deficiencies on the Confidential Statement of Formula that have not been addressed [redacted] and [redacted] remain unapproved inerts and we do not show that any petitions have been received by the Agency.

In addition, as indicated in Keri's letter, we still need full compositional information for [redacted] to ensure that there are not other unapproved inerts included in those trade name products. Compositional information needs to be on the manufacturers company letterhead and includes the full product name and the chemical name, CAS No., and %(by wt) in formulation of each component-components must total 100%. This information may be submitted directly to the agency.

Please let me know if you need any more information or have any questions.

Thanks,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch
fertich.elizabeth@epa.gov
703-347-8560

Linda Hollis Elizabeth Raderrio Wilkins (the regulatory pers... 03/04/2009 03:05:31 PM

From: Linda Hollis/DC/USEPA/US
To: Elizabeth Fertich/DC/USEPA/US@EPA, Pv Shah/DC/USEPA/US@EPA
Cc: Karen Samek/DC/USEPA/US@EPA
Date: 03/04/2009 03:05 PM
Subject: Re: [redacted]/Approval letter

Elizabeth: Raderrio Wilkins (the regulatory person assigned to this case) has informed me that there are 3 more [redacted] that are not approved. Does your request contain a petition for only one. Raderrio has a letter from Keri Grinstead which states what needs to be petitioned and therefore cleared. I really need to get this clarified. Do you need a copy of the letter to check?

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard

2777 S. Crystal Drive
Arlington, VA 22202
hollis linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

Elizabeth Fertich Hi Linda, Here is the copy of the approval letter. . 03/04/2009 02:01:19 PM

Inert ingredient information may be entitled to confidential treatment

Re: Catnip (EPA File Symbols 71654-EG and ER)
Raderrio Wilkins to: Linda Hollis 04/08/2009 12:41 PM

Linda,

To date, IIAB is not in receipt of any new inert ingredient requests, petitions or correspondences regarding the three CAS numbers [redacted] nor has the registrant responded to the Agency's deficiency letter of November 13, 2008 (Product Chem., Uncleared Inerts, Chemical identification etc..) If I recall correctly, the inert reviewer was Ms Elizabeth Fertich, I will contact her to obtain her review

Raderrio

Linda Hollis Raderrio: John Redden has agreed to do a Han... 04/08/2009 12:16:06 PM

From: Linda Hollis/DC/USEPA/US
To: wilkins.raderrio@epa.gov
Date: 04/08/2009 12:16 PM
Subject: Catnip

Raderrio: John Redden has agreed to do a Hand to Mouth Assessment for the Catnip products. This should determine how we move forward with the other products provided the inerts are cleared. You will need to do two things and this is to be done immediately.

1. Contact PV Shahs group for the reviewer of the inerts petition and request a copy of the reviews.

2. Bean a copy of that information, our tox review and label to John Redden. He has agreed that you can just give it to him straight. John may need additional information so please provide if he does.

Thirdly, I am unclear to date as to whether or not the supplier has petitioned the Agency for clearance for the other inerts.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

Notes:
As of 4/15/09, Dupont Chemical has not petitioned the Agency / IIAB for clearance of the remaining three chemicals.
R. Wilkins

Inert ingredient information may be entitled to confidential treatment

Re: Fw: [redacted]/Approval letter
Raderrio Wilkins to: Linda Hollis 03/04/2009 02:57 PM
Cc: andersen.janet

Linda,

Please resend the approval letter for [redacted] I can open the attachment. In addition, the products (EPA File Symbols 71654-EG and ER) contains three other chemicals [redacted] not approved for use as inert ingredients in pesticides. To my knowledge, I am not aware of IIAB being in receipt of any new inert ingredient requests, petitions or correspondences regarding the three CAS numbers nor has the registrant responded to the Agency's deficiency letter of November 13, 2008.

Sincerely,
Raderrio

Linda Hollis The [redacted]) contained in th... 03/04/2009 02:09:29 PM

From: Linda Hollis/DC/USEPA/US
To: wilkins.raderrio@epa.gov
Cc: andersen.janet@epa.gov
Date: 03/04/2009 02:09 PM
Subject: Fw: [redacted]Approval letter

The [redacted]) contained in the Catnip formulations have been cleared by the inerts branch for non food use. See letter below. The registrant successfully petitioned the Agency. We should be well on our way with completion for the remaining products.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
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(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

---- Forwarded by Linda Hollis/DC/USEPA/US on 03/04/2009 02:07 PM ----

From: Elizabeth Fertich/DC/USEPA/US
To: Linda Hollis/DC/USEPA/US@EPA
Cc: Pv Shah/DC/USEPA/US@EPA, Karen Samek/DC/USEPA/US@EPA
Date: 03/04/2009 02:01 PM
Subject: [redacted]Approval letter

Inert ingredient information may be entitled to confidential treatment

Hi Linda,

Here is the copy of the approval letter you requested when speaking to Karen Samek. If you need anything else please let me know.

[attachment "Acceptance letter for [redacted].pdf" deleted by Linda Hollis/DC/USEPA/US]

Thanks,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch
fertich.elizabeth@epa.gov
703-347-8560

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 371862	**Registration#:** 71654-ER	**Petition #:** N/A
Fee Category: B60 (PRIA 1)	**PRIA Decision Time Frame:** 12 months	
Submitted by: Raderrio Wilkins	**Branch: BPB**	**Date:** November 26, 2008
Company: Dupont Chemical Solution		
Original Due Date: Nov. 17, 2007	**Proposed New Due Date:** July 31, 2009	
Previous Negotiated Due Dates: 11/17/07, 5/30/08, and 11/30/08		
Is the "Fix" in-house? No	**If not, date "Fix" expected: February 28, 2009**	

Issue (describe in detail):
In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (change in four inerts or submit inerts substantially similar). The Agency received the resubmitted data package in mid-March which partially addressed the Agency's concerns. The product contains four inerts in the formulation that are not cleared for use which the registrant did not address in their resubmission as requested in the Agency's letter of October 16, 2007. To date, the product chemistry data remain incomplete.

Summary of Deficiency Type(s): **Not Submitted (N)** **Deficiencies (D)**
Product Chemistry: __D__ **Acute Tox:** ____ **Efficacy:** _D__ **Labeling:** ____ **Other (describe):** ____

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The company's agent (Mr. Thomas McEntee) is extremely slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief.

"75 Day" Letter sent? 10/16/07 and 11/13/08 (Date sent) **Yes** ____**No and reason for none?**

Note: Application was submitted under PRIA 1

Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases III – V, which is equivalent to 8 months. The registrant must submit an application for inert clearance to RD, in addition to addressing other deficiencies.

Registrant notified that this is the last negotiation? ___X__**Yes** ___ submission was submitted and____

Approve: ✓	**Disapprove:**
If disapproved, action to be taken:	
OD or DOD Signature: [signature]	**Date:** 11/28/08

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
11/26/2008 12:44 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Re: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates to the calenar year 2009

Ms. Linda Hollis,

This will confirm the negotiated dates are in calenar year 2009 as you have detailed below.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

11/26/2008 12:07 PM

To Thomas C McEntee/AE/DuPont@DuPont
cc wilkins.raderrio@epa.gov
Subject Re: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates

Thank you, but there are some errors. The dates reflect year 2008. The dates should be the following:

71654-EN December 5, 2008

71654-EL and EU March 31, 2009

71654-EG and ER July 31, 2009 with the understanding that the Agency may likely to renegotiate again if the the Agency is not in receipt of all of the missing information, to include submission of the inert information to the Registration division by February 28, 2009.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
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Arlington, VA 22202

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(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

11/26/2008 12:00
PM

To
Linda Hollis/DC/USEPA/US@EPA

cc
Raderrio Wilkins/DC/USEPA/US@EPA

Subject
Refined Oil of Nepeta cataria --
Renegotiated PRIA Action Dates

Ms. Linda Hollis,

This is to confirm our November 26, 2008 telephone conference regarding the
need to renegotiate PRIA dates for the following applications for registration.

File Symbol	Product	Date	
71654-EN	Technical	December 5, 2008	(accomodate review of new active ingredient fact sheet)
71654-ER	15% Lotion	July 31, 2008	(acquire detail from inert supplier by Feb. 28, 2009 or further renegotiate)
71654-EG	7% Lotion	July 31, 2008	(same as 71654-EG)
71654-EL	15% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series)
71654-EU	7% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series from 71654-EL)
All			(re-review MRID 47362603 - Supplemental Efficacy Explanations; after the fact HSRB upgrades)

If you have any questions, please feel free to call or e-mail.

Thank you for your assistance with our application.

Enjoy the Thanksgiving Holiday.

Tom McEntee
302 695 6856
978 335 8055 CELL

Product ingredient source information may be entitled to confidential treatment

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
11/05/2008 09:31 AM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Re: Status of Catnip Pending product applications

Ms. Linda Hollis,

Thank you for the e-mail. I look forward to the receipt of the deficiency letters.

I have been in contact with [redacted] after he was able to return to his office following Hurricane Ike.

I do expect to submit a renegotiated PRIA date for the formulations which you have been handling. I'll endeavor to detail the date at which we expect to submit the information on the inert or have it submitted directly to you.

Thank you for all of your efforts with the applications and successful completion of the technical grade product.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

10/31/2008 09:06 AM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
wilkins.raderrio@epa.gov
Subject
Status of Catnip Pending product applications

Dear Mr. McEntee: I am providing to you the status of the Catnip pending applications. I do have good news and will provide that for you first. The techncial product application will be registered by the pria due date of November 30, 2008. With regard to all of the he remaining end use products which will be formulated with TGAI material, they are deficient and will need to be renegotiated. For some time now there has been a serious issue with regard to one of the inert components in the formulations, i.e., the propiertary blend, the components of this blend unfortunately are not cleared. We have been in communication with you earlier this year and Karen Angulo did provide you with guidance as to

???

how to proceed with the supplier of this blend. If fact, we do have record of contact with [redacted] who has provided us with information, but unfortunately, not what we need. Communication on the part of [redacted], did cease, and for that reason, we still are unable to process or clear the components of the blend. You will be receiving a detailed deficiency letter in the mail within the next week. However, I need to communicate to you your regulatory options. You will either need to renegotiate the due date for this products to be in line with how soon [redacted] will be able to make the formal request to the inerts branch as to what is needed and submit the information, in addition to addressing the data deficiencies that still remain with this products. Again, [redacted] is aware of what is needed and how to submit as told to him by EPA staff in the Inerts Branch. This information must come directly from the supplier. Should you not renegotiate and not make contact with the Agency, either myself or Mr. Wilkins, then we will proceed with the issuance of a can not grant letter by or on November 30, 2008. As explained to you in earlier letters, a can not grant letter will essentially put you out of a scheduled work frame, i.e., no longer pria. We can still work on your application, but there will be no scheduled time. Should you elect to renegotiate the date, keep in mind that Inert Clearance falls within the scope of the Registration Division. They have indicated that they will need four to five months to clear this inert, this time should be added to the amount of time that BPPD will need to conduct review (of the resubmitted information per the deficiency letter that is to come) and make a regulatory decision. Having said this, the total amount of renegotiated time will most likely be 8 months.

Your urgent response is requested.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
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Visit http://www.epa.gov/pesticides

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

11/26/2008 12:00 PM

To: Linda Hollis/DC/USEPA/US@EPA
cc: Raderrio Wilkins/DC/USEPA/US@EPA
Subject: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates

Ms. Linda Hollis,

This is to confirm our November 26, 2008 telephone conference regarding the need to renegotiate PRIA dates for the following applications for registration.

File Symbol	Product	Date	
71654-EN	Technical	December 5, 2008	(accomodate review of new active ingredient fact sheet)
71654-ER	15% Lotion	July 31, 2008	(acquire detail from inert supplier by Feb. 28, 2009 or further renegotiate)
71654-EG	7% Lotion	July 31, 2008	(same as 71654-EG)
71654-EL	15% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series)
71654-EU	7% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series from 71654-EL)
All			(re-review MRID 47362603 - Supplemental Efficacy Explanations; after the fact HSRB upgrades)

If you have any questions, please feel free to call or e-mail.

Thank you for your assistance with our application.

Enjoy the Thanksgiving Holiday.

Tom McEntee
302 695 6856
978 335 8055 CELL

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 13 2008

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

Re: Application for a new Biochemical pesticide Registration
Refined Oil of *Nepeta cataria*
EPA File Symbol. No.: 71654-EN (TGAI), -EG , -ER,
PRIA Due Date November 30, 2008

Dear Mr. McEntee:

Please refer to my email dated May 28, 2008 and deficiency letter dated April 16, 2008. Your application remains deficient and we can not proceed with reviewing your application for the end use formulations with the inert clearance issue being unresolved. We renegotiated the Pria due dates for your products to reflect a date of November 30, 2008 with the understanding that you would address the "all" of the deficiencies identified in the Agency's letter dated October 16, 2007, along with submitting the materials necessary for the Inerts Branch to review and possibly resolve. BPPD was informed by Karen Angulo and ~~Prakasheha Shah~~ of the Inerts Branch that you have not submitted the requested information in a formal request or petition to have the inerts reviewed for clearance.

Therefore, your applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

I. CSF

EPA File Symbol 71654-EG (7% Lotion)

a. Provide a complete address and CAS registry number for the component [redacted]

b. Please change the CAS No. for [redacted]

c. Please provide a CAS No. for the active ingredient.

d. [redacted] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [redacted] on the CSF.

f. Please address the discrepancy of why the content of [redacted] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [redacted] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

EPA File Symbol 71654-ER (15% Lotion)

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

II. PRODUCT CHEMISTRY

File Symbol 71654-EG (7% Lotion)

a. Please provide a rationale for the increase in percent weight of [redacted] in the 7% lotion when compared to the TGAI.

b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.

c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB – Pv Shah, Shah.Pv@epa.gov).

[redacted]

File Symbol 71654-ER (15% Lotion)

a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

III. PHYSCIAL PROPERTIES

File Symbol 71654-EG (7% Lotion)

a. Please address oxidation/reduction: chemical incompatibility and explodability.

b. Submit storage stability and corrosion characteristics tests upon their completion.

File Symbol 71654-ER (15% Lotion)

a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are **ACCEPTABLE.**

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to nontarget organisms. Please address the data requirements by submitting data or a request to waive the data requirement (the data matrix must reflect this request along with MRIDs and rationale for waiving).

IV. PRODUCT PERFORMANCE

a. Please provide detailed discussion on the statistics employed to analyze the data.

b. Please address the inconsistencies concerning the amount of test material applied to subjects.

c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).

d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there is not enough time remaining before the PRIA decision date of November 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. The deficiencies outlined above for the three end use products in addition to review and clearance of the inert ingredients contained in the proprietary blend will require EPA review and regulatory decision making of 8 months post the date that the information is resubmitted to the Agency.

Therefore, you may renegotiate the due dates for the three products above, or withdraw the applications and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response. Again, we will require an extension time of 8 months post the date that you expect to make a full resubmission of the information. We can not renegotiate the date based on a partial submission. You should allow yourself adequate time for your supplier of the proprietary blend to make the submission (officially) to the Agency in addition to enough time for Dupont to address the above the deficiencies. We must have confirmation of a renegotiated due date from you via email by the close of business on November 20, 2008.

As stated above, the request for clearance of the components in the proprietary blend must be submitted to the Agency from the supplier. The EPA has communicated with your supplier and has indicated what information the Agency will need. Given that this information is confidential, we can tell you that the request must be officially submitted to the Agency to the attention of the Inerts Branch of the Registration Division. The request will be for a petition and must state so. The request or formal submission must petition the Agency for food or non food clearance and must contain the components and amount in the blend. Once received and deemed sufficient, this request for clearance will be scheduled. I strongly suggest that you coordinate the

timing of this submission and the submission which will address the above product chemistry issues. Again, partial submissions will not be considered.

Sincerely,

Linda A. Hollis., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CC:
Pv Shah
Kerry Leifer

Product ingredient source information may be entitled to confidential treatment

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
11/05/2008 09:31 AM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Re: Status of Catnip Pending product applications

Ms. Linda Hollis,

Thank you for the e-mail. I look forward to the receipt of the deficiency letters.

I have been in contact with [redacted] after he was able to return to his office following Hurricane Ike.

I do expect to submit a renegotiated PRIA date for the formulations which you have been handling. I'll endeavor to detail the date at which we expect to submit the information on the inert or have it submitted directly to you.

Thank you for all of your efforts with the applications and successful completion of the technical grade product.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

10/31/2008 09:06 AM

To Thomas C McEntee/AE/DuPont@DuPont
cc wilkins.raderrio@epa.gov
Subject Status of Catnip Pending product applications

Dear Mr. McEntee: I am providing to you the status of the Catnip pending applications. I do have good news and will provide that for you first. The technical product application will be registered by the pria due date of November 30, 2008. With regard to all of the he remaining end use products which will be formulated with TGAI material, they are deficient and will need to be renegotiated. For some time now there has been a serious issue with regard to one of the inert components in the formulations, i.e., the propiertary blend, the components of this blend unfortunately are not cleared. We have been in communication with you earlier this year and Karen Angulo did provide you with guidance as to

???

how to proceed with the supplier of this blend. If fact, we do have record of contact with [redacted] who has provided us with information, but unfortunately, not what we need. Communication on the part of [redacted], did cease, and for that reason, we still are unable to process or clear the components of the blend. You will be receiving a detailed deficiency letter in the mail within the next week. However, I need to communicate to you your regulatory options. You will either need to renegotiate the due date for this products to be in line with how soon [redacted] will be able to make the formal request to the inerts branch as to what is needed and submit the information, in addition to addressing the data deficiencies that still remain with this products. Again, [redacted] is aware of what is needed and how to submit as told to him by EPA staff in the Inerts Branch. This information must come directly from the supplier. Should you not renegotiate and not make contact with the Agency, either myself or Mr. Wilkins, then we will proceed with the issuance of a can not grant letter by or on November 30, 2008. As explained to you in earlier letters, a can not grant letter will essentially put you out of a scheduled work frame, i.e., no longer pria. We can still work on your application, but there will be no scheduled time. Should you elect to renegotiate the date, keep in mind that Inert Clearance falls within the scope of the Registration Division. They have indicated that they will need four to five months to clear this inert, this time should be added to the amount of time that BPPD will need to conduct review (of the resubmitted information per the deficiency letter that is to come) and make a regulatory decision. Having said this, the total amount of renegotiated time will most likely be 8 months.

Your urgent response is requested.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

UNITED STATES ENVIRONMENTAL PROTECTION AGEN
WASHINGTON, D.C. 20460

OFFICE
PESTICIDES, AND TO

October 28, 2008

MEMORANDUM

Subject: Inert Ingredient Review of the proposed Confidential Statements of Formula for 71654-EG (12/5/2006) and 71654-ER (10/19/2006)

From: Keri Grinstead
Inert Ingredient Assessment Branch
Registration Division

To: Raderrio Wilkins
Biopesticides and Pollution Prevention Division

The Inert Ingredient Assessment Branch (IIAB) has reviewed the inert ingredients on the proposed Confidential Statements of Formula for the products listed above. Based on this review, IIAB confirms that the following CAS numbers remain not approved for use as inert ingredients in pesticide products: [redacted] Any trade name or proprietary blend products containing these CAS numbers are also not approved for use as inert ingredients. Additionally, the CAS number listed for [redacted] is not valid and the Agency is lacking full compositional information for the following trade name products: [redacted]. Full compositional information for trade name products is necessary for the Agency to verify/review the components for approval.

Some information was received by IIAB for [redacted] however, this information was determined to be insufficient for further IIAB review. The submitter was notified that additional information was necessary and, to date, no further response or information has been received regarding this CAS number. Additionally, IIAB has not received any new inert ingredient requests, petitions, or correspondence regarding the other three CAS numbers [redacted]

Based on this information, the above CAS numbers remain ineligible for use as inert ingredients in pesticide products. For future reference, all inert ingredients on a proposed CSF must be approved for the product's labeled uses prior to the Agency granting a registration.

Information regarding inert ingredients permitted in pesticide products can found on the inerts website at http://www.epa.gov/opprd001/inerts/lists.html. Guidance for submitting a new inert ingredient request/petition and/or submitting compositional information can be obtained by emailing IIAB at InertsBranch@epa.gov or calling Keri Grinstead at 703-308-8373.

Please let me know if I can be of further assistance.

Sincerely,

Keri Grinstead

Keri Grinstead (703)308-8373
Inert Ingredient Assessment Branch
Registration Division

Information regarding inert ingredients permitted in pesticide products can found on the inerts website at http://www.epa.gov/opprd001/inerts/lists.html. Guidance for submitting a new inert ingredient request/petition and/or submitting compositional information can be obtained by emailing IIAB at InertsBranch@epa.gov or calling Keri Grinstead at 703-308-8373.

Please let me know if I can be of further assistance.

Sincerely,

Keri Grinstead

Keri Grinstead (703)308-8373
Inert Ingredient Assessment Branch
Registration Division

Raderrio Wilkins/DC/USEPA/US
09/30/2008 06:15 PM

To Linda Hollis/DC/USEPA/US@EPA
cc
bcc
Subject The status on the Catnip Products (71654-EG, ER, EU and EL)

Linda,

Per your request, I summarized the status of the Catnip products for your information (details listed below).

EPA File Symbol 71654-EN (TGAI):

1. The registrant addressed the Product chemistry for the TGAI in MRIDs (47362601 and 47362602).

2. The registrant must submit storage stability and corrosion characteristics tests.

3. The Tier I Toxicity studies have previously been termed **ACCEPTABLE** (Gardner to Wilkins 10/04/07; Wilkins to McEntee 10/16/07). DuPont submitted a discussion (MRID 47362604) that addressed the questions EPA had regarding a positive mouse lymphoma assay. The discussion provided an **ACCEPTABLE** rationale for the TGAI being non-genotoxic and explores the concept of false test positives and weight of the evidence.

4. Although product performance data is not required for the registration of the TGAI (Refined oil of *Nepeta cataria*), however DuPont responded to the study deficiencies by submitting a supplement (MRID 47362603) to the previously submitted **UNACCEPTABLE** study. **The supplement satisfactorily addressed the scientific deficiencies present in the original studies, however ethical issues still have not been resolved and may need further review (Classification remains UNACCEPTABLE, but upgradable).**
In particular, ethical questions involve, but are not limited to:

1) The use of employees of Insect Control & Research in mosquito bite-testing,
2) The lack of monitoring information on local mosquito-borne vectors prior to testing,
3) Other issues identified in a previous review (Fuentes to Wilkins 10/04/07).

EPA File Symbol 71654-ER and EG (EPs):

1. Product chemistry and CSF deficiencies for the 7% (71654-EG) and 15% (71654-ER) lotion have not been addressed as requested (Wilkins to McEntee, 10/16/07). I am not in receipt of any resubmission for products 71654-ER, **EG, EU or EL.**

Sincerely,
Raderrio

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 371862	**Registration#:** 71654-ER	**Petition #:** N/A
Fee Category: B60 (PRIA 1)	**PRIA Decision Time Frame:** 12 months	
Submitted by: Raderrio Wilkins	**Branch: BPB**	**Date:** May 19, 2008
Company: Dupont Chemical Solution		
Original Due Date: Nov. 17, 2007	**Proposed New Due Date:** November 30, 2008	
Previous Negotiated Due Dates: 5/30/08		
Is the "Fix" in-house? No	**If not, date "Fix" expected: 6/13/08**	

Issue (describe in detail):
In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, species etc.), and Mutagenicity Study (Point Mutag. Assay to validate or confirm results) for products 71654-EN, -ER, -EG, _EU and -EL by the end February 2008 to support the bridging of data. The Agency received the resubmitted data package in mid-March. Furthermore, the product contain four inerts in the formulation that are not cleared for use which the registrant did not address in their resubmission as outlined in the Agency's letter of October 16, 2007. Failure to submit the missing data by the end of February impacted the new Pria Date of May 30, 2008. To date, the information as resubmitted remains incomplete.

Summary of Deficiency Type(s): **Not Submitted (N)** **Deficiencies (D)**
Product Chemistry: __D__ **Acute Tox:** __D__ **Efficacy:** _D__ **Labeling:** ____ **Other (describe):** ____

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The company's agent (Mr. Thomas McEntee) is extremely uncooperative and slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief.

"75 Day" Letter sent? 10/16/07 (Date sent) **Yes** ____**No and reason for none?**

Note: Application was submitted under PRIA 1

Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases II – V, which is equivalent to 6 months. The 180 day extension would allow the registrant time to resolve their formulation problem by change the four inert to a substantially similar chemical or submit an application for inert clearance to RD.

Registrant notified that this is the last negotiation? ___X__**Yes** ___ submission was submitted and___ **Not Applicable**

Approve:	**Disapprove:**
If disapproved, action to be taken:	
DD or DOD Signature:	**Date:** 5-29-08

Inert ingredient information may be entitled to confidential treatment

Linda Hollis/DC/USEPA/US
05/28/2008 09:09 PM

To "Thomas C McEntee" <Thomas.C.McEntee@usa.dupont.com>, Pv Shah/DC/USEPA/US@EPA, Karen
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Re: e-courtesy copy -- formal request to add inert

It has been noted that this is a courtesy copy. The Agency will act on an official copy submitted to the document processing center per my last email to you. Once submitted, the -nerts branch will determine if the information is sufficient to review.
to ----------\Sent by EPA Wireless E-Mail Services.

----- Original Message -----
From: Thomas C McEntee [Thomas.C.McEntee@usa.dupont.com]
Sent: 05/28/2008 04:45 PM AST
To: Pv Shah; Karen Angulo
Cc: Linda Hollis; Raderrio Wilkins
Subject: e-courtesy copy -- formal request to add inert

Dr. PV Shah and Ms. Karen Angulo,

The attached file was expressed to IIAB today.

If you have any questions, please feel free to call or e-mail.

(See attached file: 20080528 BINDER Signed Cover PV Shah 7% and 15% LOTIONs [redacted].pdf)

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov
05/28/2008 01:31 PM

To Thomas C McEntee/AE/DuPont@DuPont
cc Wilkins.Raderrio@epamail.epa.gov, Shah.Pv@epamail.epa.gov, andersen.janet@epa.gov
Subject Re: Resubmission of Information 71654 - ER and EG

Dear Mr. McEntee:

Your application remains to be deficient and we can not proceed with review of the applications for the end use formulations with the inert clearance issue being usresolved. We renegotiated the PRIA due date for your product to reflect a date of November 2008 with the understanding that in doing so, the materials necessary for the Inerts Branch to review and possibly resolve the inerts issue were in house and were in the queue. I have learned as of yesterday in a conversation with both Karen Angulo and Prakashcha Shah (Pv Shah) of the Inerts Branch that you have not submitted a formal request or petition to have the inert reviewed for clearance. You indicated in an email to Karen Angulo information that you intended to present at the presubmission meeting scheduled for April 23, 2008. Unfortunately, you did not show up for the meeting and the Inerts Branch has to date not received any formal submission from you. It is also unclear from your email to Karen Angulo whether or not your interest lies in clearance for a food or non food use. At any rate, the email to K. Angulo, does not suffice or negate the need for you to make a formal submission. The information submitted in the email, per the Inerts group is not sufficient for them to consider, further, your request, per the Inerts Group is not currently on their schedule. In order for the Inerts Group to review your request, they will need an official/formal request/petition. The Inerts group will not add you to their schedule until your and successfully completed the following steps:

1) submit a formal submission (non-food) and or petition (food) to IIAB, and;

2) It is determined by the Inerts Group that it is sufficient to work on. When this determination is made, the Inerts group may be able to give you an estimated completion timeframe.

This missing information will affect your new due date as the time frame was calculated based on the understanding that your information had been officially submitted and was being reviewed. As a result, you will only have 75 days from the date of this email (August 11, 2008) to officially submit the above information through the EPA Document Processing Center. Failure to submit the information by August 11, 2008 will result in a can not grant for the end use applications.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

Thomas C McEntee

<Thomas.C.McEntee@usa.dupont.com>

05/28/2008 10:55 AM

To: Linda Hollis/DC/USEPA/US@EPA, Raderrio Wilkins/DC/USEPA/US@EPA

cc:

Subject: Re: Resubmission of Information 71654 - ER and EG

(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf)

Mr. Raderrio Wilkins,

Refer to the cover letter from May 8, 2008 and the added page from EPA DER 9/19/07. Following the November 20067 meeting with you, the formulas were revised to substitute chemically and functionally equivelant ingredients which are on EPA's list with the exception of one inert. This inert is the subject of the submission to IIRB on April 30, 2008.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

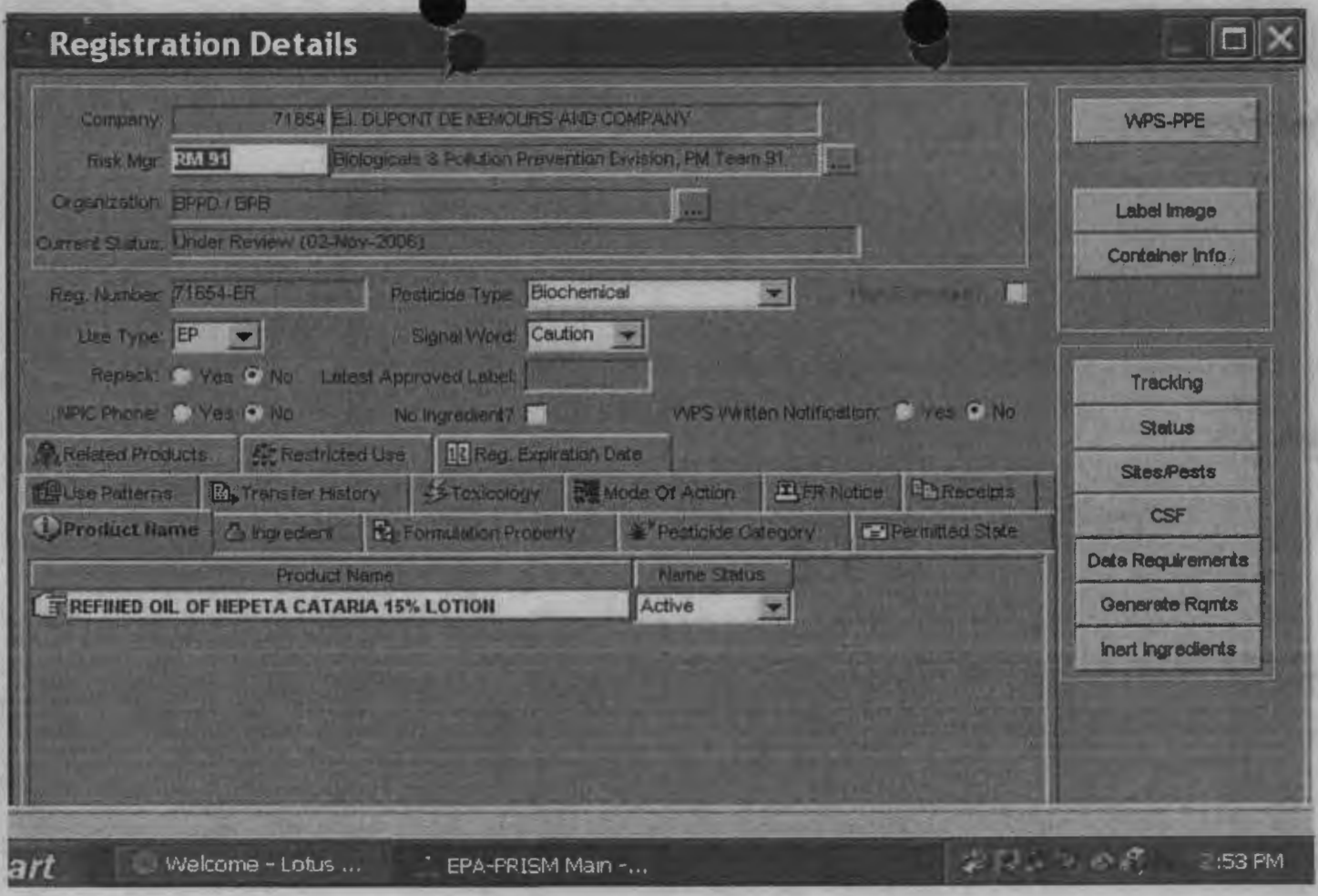
To

05/13/2008 11:53 AM

Thomas C McEntee/AE/DuPont@DuPont, Wilkins.Raderrio@epamail.epa.gov

cc

Subject: Re: Resubmission of Information 71654-EN, ER, EG and EL


Registration Details
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91
Organization: BPPD / BPB
Current Status: Under Review (02-Nov-2006)
Reg. Number: 71654-ER
Pesticide Type: Biochemical
Use Type: EP
Signal Word: Caution
Repack: Yes No
Latest Approved Label:
NPIC Phone: Yes No
No Ingredient?
WPS Written Notification: Yes No
Related Products
Restricted Use
Reg. Expiration Date
Use Patterns
Transfer History
Toxicology
Mode Of Action
FR Notice
Receipts
Product Name
Ingredient
Formulation Property
Pesticide Category
Permitted State
Product Name
Name Status
REFINED OIL OF NEPETA CATARIA 15% LOTION
Active
WPS-PPE
Label Image
Container Info
Tracking
Status
Sites/Pests
CSF
Data Requirements
Generate Rqmts
Inert Ingredients
art
Welcome - Lotus ...
EPA-PRISM Main -...
2:53 PM

MAY 2 2 2008

I believe that your submission was submitted late in addition to the fact that there were deficiencies outlined in our letter which you have not addresses in your resubmission. I am unclear as to your involvement with the inerts group for clearance however the information as resubitted thus far remain deficient. You may either renegotiate or we will elect to issue a can not grant. Alternatively, you can withdraw.

------Original Message------
From: Thomas C McEntee
To: Raderrio Wilkins
To: Linda Hollis
Sent: May 13, 2008 11:06 AM
Subject: Fw: Resubmission of Information 71654-EN, ER, EG and EL

Mr. Raderrio Wilkins,

Thank you for your telephone call. I am still trying to confirm that IIRB
has received the documents on the unlisted inert from our supplier, which
affect the review cycle for the end-use formulated lotions.

Returning to the previous negotiated date for the Nepeta catariaTechnical
and Manufcaturing Use Product (71654- EN) [EPA letter of Nov. 8, 2007], the
PRIA date was May 30, 2008. We met the target date of February 2008 for
re-submission. Extension of the PRIA date out to November for the technical registration does not seem justified.

Please let me know of any developments which are a basis for your suggestion of a November date for the technical registration.

Thank you for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL
----- Forwarded by Thomas C McEntee/AE/DuPont on 05/13/2008 10:44 AM -----

Thomas C McEntee/AE/DuPont	
To	
05/06/2008 05:54 PM	Hollis.Linda@epamail.epa.gov@DUPONT_MHUB
cc	
wilkins.raderrio@epa.gov	
Subject	
Re: Fw: Resubmission of Information 71654-EN, ER, EG and EL (Document link: Thomas C McEntee)	

Inert ingredient information may be entitled to confidential treatment

Ms. Linda Hollis,

Thank you for your e-mails. I will be completing the submissions on the end-use formulas this week.

This is to confirm that I will request a renogotiated action date for the
applications in the subject family, based on the complexity and date of last submission.

"Refined Oil of Nepeta catariaTechnical and Manufcaturing Use Product"
EPA
File Symbol 71654-EN
"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER
"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG
"Refined Oil of Nepeta cataria" 7% Liquid; EPA File Symbol 71654-EU
"Refined Oil of Nepeta cataria" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007
EPA letter of August 29, 2007
EPA letter of April 16, 2008
EPA-Dupont November 8, 2007 meeting

(See attached file: [redacted]

------Original Message Truncated------

to ----------\Sent by EPA Wireless E-Mail Services.

(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf)[attachment "20080528 Resend cover letter inert Lotion substitue.pdf" deleted by Thomas C McEntee/AE/DuPont]

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http://www.DuPont.com/corp/email_disclaimer.html

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

May 14, 2008

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Renegotiated PRIA Due Dates
"Refined Oil of *Nepeta cataria* Technical; EPA File Symbol 71654-EN
"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER
"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG
"Refined Oil of *Nepeta cataria*" 7% Liquid; EPA File Symbol 71654-EU
"Refined Oil of *Nepeta cataria*" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007
EPA letter of August 29, 2007
EPA letter of April 16, 2008
EPA-Dupont November 8, 2007 meeting

DuPont is accepting a renegotiated PRIA due date of November 30, 2008 which allows six months for EPA review of all of the items.

Should there be any questions, please feel free to call.

Thank you for your assistance with our applications.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695 6856

Karen Angulo/DC/USEPA/US
05/27/2008 03:43 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA, Pv Shah/DC/USEPA/US@EPA
bcc
Subject Fw: confirmation of receipt and pre-submission conference "Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER "Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

Hello Linda,

Here is the email from Tom McEntee. It appears he is interested in food and non-food approval, but this is not clear. This is what he was going to explain during the pre-submission meeting in April, but he canceled that meeting. The next thing we received from him was the email below. We need him to submit more than what he has and submit a formal request/petition. What he has sent is not sufficient for us to consider. His request is not currently on our schedule, and will not be added to our schedule until he 1) submits his formal submission (non-food) and or petition (food) to IIAB, and 2) we determine it is sufficient to work on. At that time we may be able to give you an estimated completion timeframe.

Thanks,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch (IIAB)
703-306-0404
angulo.karen@epa.gov

---- Forwarded by Karen Angulo/DC/USEPA/US on 05/27/2008 03:28 PM ----

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>
05/09/2008 12:57 PM

To Karen Angulo/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
Subject confirmation of receipt and pre-submission conference "Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER "Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

(See attached file: [redacted] Letter of Authorization [redacted].pdf)

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

Hello Karen,

Can you let me know if it can be confirmed that a re-qualification has been initiated relative to the product mentioned in the above letter? Can we discuss by phone or schedule a conference to get an estimate of the time required for your branch to complete the risk assessment? Do you need any other information to link the submission to our application?

BPPD has indicated the need to allow time for your assessment, so in order to negotiate a new PRIA target date, I would like to get your estimates.

I am still trying to finalize access to confidential information for other inert ingredients for a pre-application consultation. These different ingredients would be required for completely different technology than the immediate situation with the resubmissions.

Thank you for your assisstance to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

Angulo.Karen@epamail.epa.gov
04/15/2008 12:37 PM

To: Thomas C McEntee/AE/DuPont@DuPont
cc: Shah.Pv@epamail.epa.gov, Leifer.Kerry@epamail.epa.gov, Samek.Karen@epamail.epa.gov, Grinstead.Keri@epamail.epa.gov, Martin.Kathleen@epamail.epa.gov
Subject: Re: Thank you and request for Pre-Submission Conference.

Hello

I scheduled your pre-submission meeting for next Wednesday, April 23rd, from 1 - 2 pm. Schedules are tight and that is the best day/time of the days you proposed. If this is not convenient for you, lets try for the following week. Would you like to do this via conference call?

Thank you,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch (IIAB)
703-306-0404
angulo.karen@epa.gov

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

04/09/2008 05:25
PM

To
Karen Angulo/DC/USEPA/US@EPA

cc

Subject
Re: Thank you and request for
Pre-Submission Conference.

Karen,

Thank you for the prompt reply,

I will be in the area on April 16 and 17th. I could meet on Wed. the
16th
after 2:00 or break away from the ACC-biocides Panel meeting on Thursday
17th.

Alternatively, April 22/Tuesday or April 23/Wednesday.

Thanks for your consideration.

Tom McEntee
302 695 6856
978 335 8055 CELL

Angulo.Karen@epam

ail.epa.gov

To

04/09/2008 04:49
PM

Thomas C McEntee/AE/DuPont@DuPont

cc

leifer.kerry@epa.gov,

shah.pv@epa.gov

Subject

Re: Thank you and request for

Pre-Submission Conference.

Hello,

We are happy to schedule a pre-submission meeting for you. It would be helpful if you let me know several dates that you are interested in.

Thank you,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
703-306-0404
angulo.karen@epa.gov

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>

04/09/2008 01:15 PM

To: Pv Shah/DC/USEPA/US@EPA, Karen Angulo/DC/USEPA/US@EPA, Kerry Leifer/DC/USEPA/US@EPA

cc:

Subject: Thank you and request for Pre-Submission Conference.

P.V. , Karen and Kerry,

Thank you and your staffs for the very illuminating meeting yesterday, The progress you are making wiill be a huge help in or efforts to develop and register newer technology. The uncertainty around inerts has been a major disincentive to investing in safer, more sustainable formulas and product forms.

This e-mail is also a request for a pre-submission meeting to discuss requirements for the following three projects with inert issues:

1. Refined Oil of Nepeta cataria Insect Repellent Lotion - BPPD

(See attached file: Pages 4&8 from Nepeta Product Chem DER Nov 2007.pdf)

The proposed lotion contained several ingredients that are common in cosmetics, but apparently not in currently registred insect repellents or other formulas.. I am still refining a re-submission to address the inerts issues.

2. Self-Sanitizing Antimicrobial coating for non-food contact surfaces in food preparation and service areas.

(See attached file: cloroxpcol_final.pdf)
http://www.epa.gov/oppad001/cloroxpcol_final.pdf

We are in an advanced state of develpment of a formula to register for the above claim. The formula requires 4 ingredients that are presently not listed.

3. Enzymatically activated in-situ Active Ingredient

We are at a mid-point development of a new antimicrobial formulation which produces the active ingredient in-situ at the point of use. The product will be used as a hard surface disinfectent. It may also be extended to laundry sanitizer and food contact use. Food contact use would be expected to require tolerance formality. It would be very valuable understand your view of risk assessment of a new enzyme. (The active ingredient is allowed at 40 CFR 180.940 without limitation as to origin).

Please let me know your availability to meet so that we can move these three projects forward.

Thank you for your assistance.

Tom McEntee
Product Registration Manager
DuPont Chemical Solutions Enterprise
302 695 6856
978 335 8055 CELL

Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html
[attachment "Pages 4&8 from Nepeta Product Chem DER Nov 2007.pdf" deleted by Karen Angulo/DC/USEPA/US] [attachment "cloroxpcol_final.pdf" deleted by Karen Angulo/DC/USEPA/US]

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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[redacted] Letter of Authorization [redacted].pdf

Inert ingredient information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

APR 1 6 2008

Re: Application for a Biopesticide Registration
Refine Oil of Nepeta cataria
EPA File Symbol: 71654-ER, EG, EN, EL and EU

Dear Mr. McEntee:

Please refer to my email dated March 13, 2008. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were not cleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a PRIA action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so.
We will therefore need to know, with some urgency how you will proceed. You have the following options:

(A). Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.

(B). Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.

(C). Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of May 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the five products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about May 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response.

Sincerely,

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Linda Hollis/DC/USEPA/US
03/13/2008 11:51 AM

To Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>
cc Driss Benmhend/DC/USEPA/US@EPA, Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Resubmission of Information 71654-EN, ER, EG and EL

Dear Mr. McEntee:

I understand that you have been in conversation with Raderrio Wilkins of my staff regarding the fact that data that was to be submitted (in agreement between Dupont and the Agency) by the end of February to address deficiencies in the above product has only arrived within the past week. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were uncleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a pria action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so.

We will therefore need to know, with some urgency how you will proceed. You have the following options.

A. Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.

B. Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.

C. Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Please respond to Mr. Wilkins in a timely fashion.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division

Pages 121-122 - *Commercial/financial information may be entitled to confidential treatment*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 07, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. JACOB J. VUKICH
E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)
MANAGER, REGISTRATION & REGULATORY AFFAIRS
1007 MARKET STREET
WILMINGTON, DE 19898-0001

Dear Mr. Vukich:

Subject: Transfer of Pesticide Registrations and Data From Company Number 71654 to Company Number 352

Pursuant to your request in your letter and transfer agreement of December 13, 2013, and subsequently received information, we have approved the transfer of the following registrations from **E.I. DUPONT DE NEMOURS AND COMPANY** (DUPONT CHEMICALS & FLUROPRODUCTS), company number **71654** to **E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)**, company number **352**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
REFINED OIL OF NEPETA CATARIA	(Chemical Solutions) 71654-20	352-901
REFINED OIL OF NEPETA CATARIA 7% LOTION	71654-21	352-902
REFINED OIL OF NEPETA CATARIA 15% LOTION	71654-23	352-903
REFINED OIL OF NEPETA CATARIA 7% LIQUID	71654-24	352-904
REFINED OIL OF NEPATA CATARIA 15% LIQUID	71654-25	352-905

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain

complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee

is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated December 13, 2013, with subsequently received information, to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,

Steve Robbins, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MR.THOMAS C. MCENTEE
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICALS & FLUOROPRODUCTS
P.O. Box 80402
WILMINGTON, DE 19880-0402

RE: L_71654_RAD_352_05_07_2014

APPENDIX A

Reference: 40 CFR § 152.98 (a) (3)

For Exclusive Use See: 7 USC § 136 et seq., (FIFRA) Sec. 3 (c) (1) (F) and 40 CFR §152.83(c)

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
46977300	Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Lotion. Transmittal of 8 Studies	E. I. DU PONT DE NEMOURS AND COMPANY	11/1/2006	Y	11/1/2016
46977301	Lotion 1630802C: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure. Project Number: 834, 16615, DUPONT/20904.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977302	Lotion 1630802C: Acute Dermal Toxicity Study in Rats. Project Number: DUPONT/20889, 16615, 673.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977303	Lotion 1630802C: Acute Eye Irritation Study in Rabbits. Project Number: DUPONT/20905, 16615, 602.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977304	Lotion 1630802C: Acute Dermal Irritation Study in Rabbits. Project Number: DUPONT/20707, 16615, 1008.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977305	Lotion 1630802C: Local Lymph Node Assay (LLNA) in Mice. Project Number: DUPONT/20161, 16615, 1234.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977306	Formulation CU 1630802C: Median Lethal Inhalation Concentration Waiver Request.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977310	Summary of Physical and Chemical Characteristics of Formulations CU 1630802C and CU 1630802D.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
46977311	Physical and Chemical Characteristics of 15 wt.% Hydrogenated Catmint Oil Lotion: Physical State, Flammability and pH. Project Number: 3280/14.	E. I. DU PONT DE NEMOURS AND COMPANY	11/1/2006	Y	11/1/2016
46977400	Submission of Product Chemistry, Toxicity, and Efficacy Data in Support of the Application for Registration of Refined Oil Of Nepeta cataria.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977401	Hydrogenated Catmint Oil: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure. Project Number: DUPONT/17740, 15926, 834.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977402	Hydrogenated Catmint Oil: Acute Dermal Toxicity Study in Rats. Project Number: DUPONT/17550, 15926, 673.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977403	Hydrogenated Catmint Oil: Acute Eye Irritation Study in Rabbits. Project Number: DUPONT/17533, 15926, 602	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977404	Hydrogenated Catmint Oil: Acute Dermal Irritation Study in Rabbits. Project Number: DUPONT/17519, 15926, 1008.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977405	Hydrogenated Catmint Oil: Local Lymph Node Assay (LLNA) in Mice. Project Number: DUPONT/17409, 15926, 1234.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977406	Hydrogenated Catmint Oil: Inhalation Median Lethal Concentration (LC50) Study in Rats. Project Number: DUPONT/17408, 15926, 721.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
46977407	Hydrogenated Catmint Oil: Subchronic Toxicity 90-Day Oral Gavage Study and Immunotoxicity 28-Day Oral Gavage Study in Rats. Project Number: DUPONT/17324, 15926, 1026	E. I. DU PONT DE NEMOURS AND COMPANY	11/1/2006	Y	11/1/2016
46977408	Hydrogenated Catmint Oil: Developmental Toxicity Study in Rats. Project Number: DUPONT/17343, 15926, 841.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977409	Hydrogenated Catmint Oil: Acute Oral Neurotoxicity Study in Rats. Project Number: DUPONT/19148, 15926, 1261.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977410	Hydrogenated Catmint Oil: Bacterial Reverse Mutation Test. Project Number: DUPONT/17471, 15926, 500.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977411	Hydrogenated Catmint Oil: In Vitro Mammalian Chromosome Aberration Study in Human Peripheral Blood Lymphocytes: Final Report. Project Number: AB15GY/341/BTL, H/26993, 15926.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977412	Hydrogenated Catmint Oil: Mouse Bone Marrow Micronucleus Test. Project Number: DUPONT/18623, 15926, 572.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977413	Hydrogenated Catmint Oil: In Vitro Mammalian Cell Gene Mutation Test (L5178Y/TK+/- Mouse Lymphoma Assay). Project Number: AB15GY/704/BTL, 15926, 1537.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977415	Hydrogenated Catmint Oil: 28-Day Repeated-Dose Dermal Toxicity Study in Rats. Project Number: DUPONT/17327, 15926, 1012	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
46977420	Physical and Chemical Characteristics of Hydrogenated Catnip Oil TGAI: Color, Physical State, Odor, Flammability, pH and Viscosity: Final Report. Project Number: 3280/17.	E. I. DU PONT DE NEMOURS AND COMPANY	11/1/2006	Y	11/1/2016
46977422	Summary of Physical and Chemical Characteristics of Technical Grade Active Ingredient: (Refined Oil of Nepeta cataria).	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977424	Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine. Project Number: G3130306001A044, 0306/313/0142.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
46977425	Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida. Project Number: G3130306001A044, 0306/313/0143.	E. I. DU PONT DE NEMOURS AND COMPANY,	11/1/2006	Y	11/1/2016
47003100	Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria.	E. I. DU PONT DE NEMOURS AND COMPANY,	112/8/2006	Y	12/8/2016
47003101	Product Identity and Composition (Refined Oil of Nepeta cataria)	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47003102	Solubility Analysis, and Storage Stability Analysis of Hydrogenated Catnip Oil (HCO) Active Ingredient project Number: P00010, P0002395.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47003103	Enforcement Analytical Method for the Active Ingredient: (Hydrogenated Catnip Oil). Project Number: DUPONT/P00010, P0002366.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
47003104	Certified Limits and Supplement to Preliminary Analysis.	E. I. DU PONT DE NEMOURS AND COMPANY	12/8/2006	Y	12/8/2016
47003105	Determination of Boiling Point and Vapor Pressure (Static Method) for a Liquid TGAI and Viscosity for Two Lotion Formulations. Project Number: DUPONT/P00011, 50487.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47003300	Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Lotion.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47003301	Identity and Composition of Formulations CU 1630802C and CU 1630802D.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47003302	Analytical Method for Formulations: Refined Oil of Nepeta cataria 15% Lotion. Project Number: 00010, 0002366, E108324/119.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47003303	Certified Limits Lotion Formulation CLI 1630802C and CLI 1630802D.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/8/2006	Y	12/8/2016
47013900	Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 7 Percent Lotion.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/27/2006	Y	12/27/2016
47013901	Physical and Chemical Characteristics of 7 wt Percent Hydrogenated Catmint Oil Lotion: Physical State, Flammability and pH: Nepeta cataria Oils. Project Number: 3280/13.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/27/2006	Y	12/27/2016

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
47015600	Submission of Toxicity and Efficacy Data in Support of the Application for Registration of Refined Oil of Nepeta cataria.	E. I. DU PONT DE NEMOURS AND COMPANY	12/28/2006	Y	12/28/2016
47015601	Hydrogenated Catmint Oil: In Vitro Kinetics in Rat and Human Skin. Project Number: 19930, 15926, 1377.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/28/2006	Y	12/28/2016
47015602	Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine. Project Number: G3130306002A121, 0306/313/0141.	E. I. DU PONT DE NEMOURS AND COMPANY,	12/28/2006	Y	12/28/2016
47113800	Submission of Efficacy Data in Support of the Application for Registration of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, and Refined Oil of Nepeta cataria 7% Lotion.	E. I. DU PONT DE NEMOURS AND COMPANY,	04/24/2007	Y	04/24/2017
47113801	Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine. Project Number: 0306/313/0141.	E. I. DU PONT DE NEMOURS AND COMPANY,	04/24/2007	Y	04/24/2017
47113802	Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine. Project Number: 0306/313/0142, G3130306001A044.	E. I. DU PONT DE NEMOURS AND COMPANY,	04/24/2007	Y	04/24/2017
47113803	Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida. Project Number: 0306/313/0143, G3130306001A044.	E. I. DU PONT DE NEMOURS AND COMPANY,	04/24/2007	Y	04/24/2017
47181300	Submission of Toxicity, Product Chemistry and Efficacy Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Liquid.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
47181301	H-27923: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure. Project Number: DUPONT/22811, 17035, 834.	E. I. DU PONT DE NEMOURS AND COMPANY	07/18/2007	Y	07/18/2017
47181302	H-27923: Acute Dermal Toxicity Study in Rats. Project Number: DUPONT/22750, 17035, 673.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181303	H-27923: Acute Eye Irritation Study in Rabbits. Project Number: DUPONT/22812, 17035, 602.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181304	H-27923: Acute Dermal Irritation Study in Rabbits. Project Number: DUPONT/22470, 17035, 1008.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181305	H-27923: Local Lymph Node Assay (LLNA) in Mice. Project Number: DUPONT/21296, 17035, 1234.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181306	H-27923: Inhalation Median Lethal Concentration (LC50) Study in Rats. Project Number: DUPONT/21690, 17035, 721.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181307	Identity and Composition of 15% Refined Oil of Nepeta cataria Liquid Formulation.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181308	Physical and Chemical Characteristics of Refined Oil of Nepeta cataria 15% (w/w) Liquid Formulation 16307048: Physical State, Flammability, pH, Viscosity and Relative Density. Project Number: 3280/33, APEX838/06.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
47181309	Certified Limits: 1630704A Liquid and 1630704B Liquid.	E. I. DU PONT DE NEMOURS AND COMPANY	07/18/2007	Y	07/18/2017
47181310	Summary of Physical and Chemical Characteristics of Formulations CU 1630704A and CU 1630704A	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181311	Supplement to Efficacy Studies Submitted Under Refined Oil of Nepeta cataria Technical and Manufacturing-Use Product: EPA File Symbol 71654-ER: 1630704A Liquid and 1630704B Liquid	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181400	Submission of Product Chemistry Data in Support the Application for Registration of Refined Oil of Nepeta cataria 7% Liquid.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181401	Identity and Composition of 7% Refined Oil of Nepeta cataria Liquid Formulation.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47181402	Physical and Chemical Characteristics of Refined Oil of Nepeta cataria 7% (w/w) Liquid Formulation 1630704A: Physical State, Flammability, pH, Viscosity, Relative Density. Project Number: 3280/32.	E. I. DU PONT DE NEMOURS AND COMPANY,	07/18/2007	Y	07/18/2017
47234300	Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Lotion.	E. I. DU PONT DE NEMOURS AND COMPANY,	01/05/2007	Y	01/05/2017
47234301	Characterization of Aged Hydrogenated Catnip Oil (HCO) Formulations.. Project Number P0002216, P00009.	E. I. DU PONT DE NEMOURS AND COMPANY,	01/05/2007	Y	01/05/2017

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
47362600	Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of the Refined Oil of Nepeta cataria.	E. I. DU PONT DE NEMOURS AND COMPANY	03/04/2008	Y	03/04/2018
47362602	Supplement: Prediction of Minor Constituents of Refined Oil of Nepeta cataria as Likely Hydrogenation Products.	E. I. DU PONT DE NEMOURS AND COMPANY,	03/04/2008	Y	03/04/2018
47362603	Supplement to 'Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Maine' (MRID 46977424), 'Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Florida' (MRID 46977425) and 'Evaluation of the Efficacy of Personal Repellents against Blackflies in Maine' (MRID 47015602).	E. I. DU PONT DE NEMOURS AND COMPANY,	03/04/2008	Y	03/04/2018
47362604	Response from DuPont to the U.S. EPA Genetic Toxicity Recommendation in 'Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of Nepeta cataria (TGAI), and Two Lotion End-Use Products'.	E. I. DU PONT DE NEMOURS AND COMPANY,	03/04/2008	Y	03/04/2018
47370400	Submission of Product Chemistry Data in Support of the Application for Registration of Nepeta cataria oils.	E. I. DU PONT DE NEMOURS AND COMPANY,	03/13/2008	Y	03/13/2018
47370401	Supplement to Preliminary Analysis: Physical and Chemical Characteristics: (Nepeta cataria oils).	E. I. DU PONT DE NEMOURS AND COMPANY,	03/13/2008	Y	03/13/2018
47422900	Submission of Product Chemistry Data in Support of the Applications for Registration of Refined Oil of Nepeta cataria 15% Lotion and Refined Oil of Nepeta cataria 7% Lotion.	E. I. DU PONT DE NEMOURS AND COMPANY,	05/13/2008	Y	05/13/2018
47422901	Supplement to Product Chemistry Requirements: (Refined Oil of Nepeta cataria).	E. I. DU PONT DE NEMOURS AND COMPANY,	05/13/2008	Y	05/13/20187

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is Exclusive Use Claimed? (Y or N)	If Yes then, Date Period of Exclusive Use Ends
47425400	Submission of Product Chemistry Data in Support of the Applications for Registration of Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid.	E. I. DU PONT DE NEMOURS AND COMPANY	05/15/2008	Y	05/15/2018
47425401	Identity and Composition of 1630704A Liquid and 1630704B Liquid.	E. I. DU PONT DE NEMOURS AND COMPANY,	05/15/2008	Y	05/15/2018
48106200	Submission of Product Chemistry Data in Support of the Registrations of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, Refined Oil of Nepeta cataria 7% Lotion, Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid.	E. I. DU PONT DE NEMOURS AND COMPANY,	05/27/2008	Y	05/27/2018
48106201	One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04.	E. I. DU PONT DE NEMOURS AND COMPANY,	05/27/2008	Y	05/27/2018

MATERIAL TO BE ADDED TO JACKET

REG #: 71654-21

Description: Refined Oil Of Nepeta Cataria 7% Lotion

if applicable, check all that are attached:		Send to CSC
☐	new stamped accepted label	
☐	new CSF	
☐	notification	
☒	other: Unacceptable Storage Stability Corrosion Characteristic Study	

Instructions:
Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

SEP 01 2010

Reviewer: Menyon Adams Date: ___ _ _

Phone: (703) 347-8496 Division: BPPD

DuPont Chemicals and Fluoroproducts
P. O. Box 80402
Wilmington, DE 19880-0402

481062-00

DuPont Chemicals and Fluoroproducts

May 21, 2010

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Refined Oil of *Nepeta cataria* technical; EPA Reg. No. 71654-20
Refined Oil of *Nepeta cataria* 15% Lotion; EPA Reg. No. 71654-23
Refined Oil of *Nepeta cataria* 7% Lotion; EPA Reg. No. 71654-21
Refined Oil of *Nepeta cataria* 15% Liquid; EPA Reg. No. 71654-25
Refined Oil of *Nepeta cataria* 7% Liquid; EPA Reg. No. 71654-24

Reference: OPPTS 830.6317 (Storage Stability)

Dear Ms. Hollis,

Please refer to the attached study, which was listed as a condition of issuance of the subject registrations.

Should there be any questions, please feel free to call or e-mail.. Thank you for your assistance with our applications.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(978) 312-1160
(302) 695-6856

Thomas C. McEntee
DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 1988-0402

Subject: Refined Oil of Nepeta Cataria 7% Lotion
EPA Registration No. 71654-21
Storage Stability and Corrosion Characteristics
Decision # 434657
Application Dated: May 21, 2010

Dear Mr. McEntee:

The Storage Stability and Corrosion Characteristics Guideline study (OPPTS 830.6317 and OPPTS 830.6320) referred to above submitted in response to the terms and conditions of registration as issued July 29, 2009 is **unacceptable but upgradeable.** The following deficiencies need to be addressed:

1. You must clearly demonstrate the stability of the two active ingredients listed on your Confidential Statement of Formula (CSF) by showing whether or not the nominal concentration of these two ingredients are within the certified limits listed on the CSF after 12 months of storage.
2. You must explain the percentage values that are below the lower certified limits for the active ingredients.
3. You must justify why sampling was not performed from each container type at each time interval.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at: adams.menyon@epa.gov.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

YMBOL ▶	7511P							
URNAME ▶	Adams							
ATE ▶	07/31/10							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: August 25, 2010

SUBJECT: Science Review of Storage Stability and Corrosion Characteristics Studies for Several Products Containing Oil of *Nepeta Cataria* as their Active Ingredient: Refined Oil of *Nepeta cataria* Technical; Refined Oil of *Nepeta cataria* 7% Lotion; Refined Oil of *Nepeta cataria* 15% Lotion; Refined Oil of *Nepeta cataria* 7% Liquid; Refined Oil of *Nepeta cataria* 15% Liquid

EPA File Symbol Numbers:	**71654-20; 71654-21; 71654-23; 71654-24; 71654-25**
Decision Numbers:	**434656; 434657; 434659; 434660; 434661**
DP Barcode:	**378691; 378694; 378693; 378696; 378695**
PC Code:	**004801**
CAS Number:	**8023-84-5**
MRID Number:	**48106201**

FROM: Gina M. Casciano, M.S., Biologist /s/ 8/25/2010
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist /s/ 8/25/2010
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

E. I. du Pont de Nemours and Company requests the review of a recently completed Storage Stability and Corrosion Characteristics study that includes five products containing *Nepeta cataria* oils as their active ingredient (MRID 48106201). Each product was granted a Conditional Section 3(c) Registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) between December 4, 2008, and March 26, 2009.

RECOMMENDATIONS AND CONCLUSIONS

1. Storage stability data presented appear to indicate that the test substance was stable for 1 year with minimum change in active ingredient concentration and no change in appearance. However, the registrant did not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their Confidential Statement of Formula (CSF). The storage stability analysis is **UNACCEPTABLE,** but upgradable. The registrant must:
    a. Demonstrate the stability of each of the two ingredients that are listed as active ingredients on the Confidential Statement of Formula (CSF). Specifically, the registrant must show whether or not the nominal concentrations of these two ingredients remain above the lowest respective certified limit after 12 months of storage.
    b. Explain those values lying outside the active ingredient certified limits for each product.
    c. Justify why sampling for each container type was not performed at each time interval.

2. The Corrosion Characteristics analysis indicates that the test substance is not corrosive to packaging materials. The corrosion characteristics data are **ACCEPTABLE;** no additional data are required.

STUDY SUMMARIES

Storage Stability

The registrant has submitted MRID 48106201 to fulfill the Storage Stability data requirement for the manufacturing-use product (MP) Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20), and end-use products (EPs) Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21), Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23), Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24), and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25). The study was conducted in accordance with OPPTS Guideline 830.6317 with the following deviations:

- Samples of each product were contained in glass and high density polyethylene (HDPE). Samples of the TGAI/MP were also contained in aluminum (Al). Not all container types were sampled at each time point during the study (0 months, 3 months, 6 months, etc).
- No sample reading were taken at 9 or 12 months. In lieu of a 12-month reading, the samples were read at T = 15 months.

All samples were stored at 25°C and 50% relative humidity for the duration of the study (June, 2001-October, 2008). For each analysis, three portions of the sample to be analyzed were weighted, mixed with a solution of the internal standard 1,2-dibromobenzene and analyzed via

gas chromatograph. (Standards used for calibration/comparison included nepetalactones, dihydronepetalactones, nepetalic acids, puleganic acids, and beta-caryophyllene.) Each of the triplicate samples was analyzed twice in a back to back fashion, thus giving six readings per sampling event. The six values are averaged and these results are displayed in Tables 1-5, below. Because the chromatography can be different for a sample when analyzed as prepared compared to the chromatography of the sample when diluted (sometimes the more concentrated peak will "tail" extensively and can cause the peak not to be within the desired window), all samples were analyzed as prepared, and also analyzed after dilution. The registrant states in their report (MRID 48106201) that the data for the "neat" or "as prepared" samples are reported for reference only, and should not be used in analysis due to the tailing of such peaks and the potentially erroneous GC readings they produce. Therefore, only the results from the diluted preparations are analyzed here.

BPPD has calculated the percent change in active ingredient for each sample. Samples were compared to T = 0 values, unless an analysis was not done at T = 0. Then, the percent change was calculated from the earliest recorded value. **The registrant must justify why sampling did not take place from each container type at each time interval.**

Table 1: Results for Refined Oil of *Nepeta cataria* Technical (EPA Reg No. 71654-20)†

	Glass		HDPE		Aluminum	
	% AI	% change	% AI	% change	% AI	% change
T = 0	96.28	n/a	n/d	n/a	n/d	n/a
T = 3 mo	n/d	n/a	85.07	n/a	83.93	n/a
T = 6 mo	92.63	-3.79	93.32	9.70	92.46	10.16
T = 15 mo	91.14	-5.34	93.95	10.44	93.13	10.96

Table 2: Results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21)†

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	6.38	n/a	n/d	n/a
T = 3 mo	n/d	n/a	5.89	n/a
T = 6 mo	n/d	n/a	6.81	15.6
T = 15 mo	6.13	-3.92	6.08	3.23

Table 3: Results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23)†

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	14.86	n/a	n/d	n/a
T = 3 mo	n/d	n/a	13.17	n/a
T = 6 mo	n/d	n/a	15.48	17.54
T = 15 mo	14.07	-5.32	14.41	9.42

Table 4: Results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24)†

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	6.32	n/a	n/d	n/a
T = 3 mo	n/d	n/a	6.19	n/a
T = 6 mo	n/d	n/a	6.87	10.98
T = 15 mo	6.59	4.27	6.5	5.01

Table 5: Results for Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25)†

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	14.00	n/a	n/d	n/a
T = 3 mo	n/d	n/a	13.76	n/a
T = 6 mo	n/d	n/a	15.46	12.36
T = 15 mo	14.20	1.41	14.59	6.03

† MRID 48106201, pp 14-15.

The results for the manufacturing-use product (MP) are listed in Table 1. This product, Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20) has an active ingredient (a.i.) concentration of 100% listed on its label and two components listed as active ingredients on its CSF. **The data presented do not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their CSF. This must be addressed.**

The end-use products (EPs) analyzed in this study were stored and sampled from glass and HDPE containers only. The results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21) are listed in Table 2. The a.i. concentration listed on the Confidential Statement of Formula (CSF) for this product is 7.0%, with upper and lower certified limits of 7.35% and 6.65%, respectively. Measured concentrations in this study range from 5.89 to 6.81 percent a.i. Specifically, ending values (T = 15 months) are 6.13% for the glass container and 6.08% for the HDPE container. These values are below the lower certified limit for the a.i. **The registrant must explain these a.i. percentage values.**

The results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23) are listed in Table 3. The a.i. concentration listed on the CSF for this product is 15.0%, with upper and lower certified limits of 15.75% and 14.25%, respectively. The ending concentration for the HDPE container was within these limits at 14.41%. The ending a.i. concentration for the glass container was 14.07, which is below the lower certified limit. **The registrant must explain this value.**

The results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24) and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25) are listed in Tables 4 and 5, respectively. Both products show a net increase in a.i. concentration over the course of the study.

However, the starting concentrations of a.i. for both products was below the lower certified limit values listed on the CSF. **The registrant must explain these values.**

CLASSIFICATION: **UNACCEPTABLE, but upgradable.** The registrant demonstrate that the two active ingredients present in their TGAI are stable within the certified limits listed on their Confidential Statement of Formula CSF. The registrant must justify why sampling for each container type was not performed at each time interval. The registrant must also explain values lying outside the active ingredient certified limits.

Corrosion Characteristics

Observations of the samples and packaging used in the above study of Storage Stability lead the study authors to conclude that the test substance is not corrosive to packaging materials. Details of these observations were not included.

CLASSIFICATION: **ACCEPTABLE,** no additional data are required.

Data Evaluation Records (DERs) were not written for this review. For additional information on these Storage Stability and Corrosion Characteristics studies, please refer to MRID 48106201.

cc: G. Casciano, M. Adams, R. S. Jones, BPPD Science Review File, IHAD/ARS
G. Casciano, Biologist, FT, PY-S: 8/25/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:	Date of Issuance:
71654-21	JUL 2 9 2009

Term of Issuance: Conditional

NOTICE OF PESTICIDE:

_____ Registration ____ Re-registration
(under FIFRA, as amended)

Name of Pesticide Product:

Refined Oil of *Nepeta cataria* 15% Lotion

Name and Address of Registrant (include ZIP Code):

DUPONT CHEMICAL SOLUTION ENTERPRISE
P.O. BOX 80402
WIL MINGTON, DE 19880-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c) (7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.

2. Submit a data package for the Guideline Study: OPPTS 830.6317 (Storage Stability), within 12 months from the date of issuance of this registration notice.

3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-21.

4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:
W. Michael McDavit

Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division

Date: 7-29-09

CONCURRENCES								
SYMBOL		7511P	7511P			7511P		
SURNAME			COLE			Hollis		
DATE			7/28/09			7/28/09		

EPA Form 8570-6

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

Refined Oil of *Nepeta cataria* 7% Lotion

Insect Repellent Lotion
Repels Mosquitoes and Black Flies

ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*.....	7.0%
Other Ingredients	93.0%
Total	100.0%

EPA Reg. No. 71654 – 23 [EG] EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

ACCEPTED
JUL 2 9 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71654-21

20090728 7% Lotion Label .doc

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing. Discontinue use and consult a doctor if irritation or rash occurs. Ask a doctor before using on children under 1 year of age.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels mosquitoes and Black Flies for up to 7 hours.

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds or freshly shaved skin,

To apply to face; apply to palms of hand and rub on skin. An adult must apply this product to children under ten years of age. Do not apply to children's hands.

For continued protection: Reapplication after six hours may be necessary.

After returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again

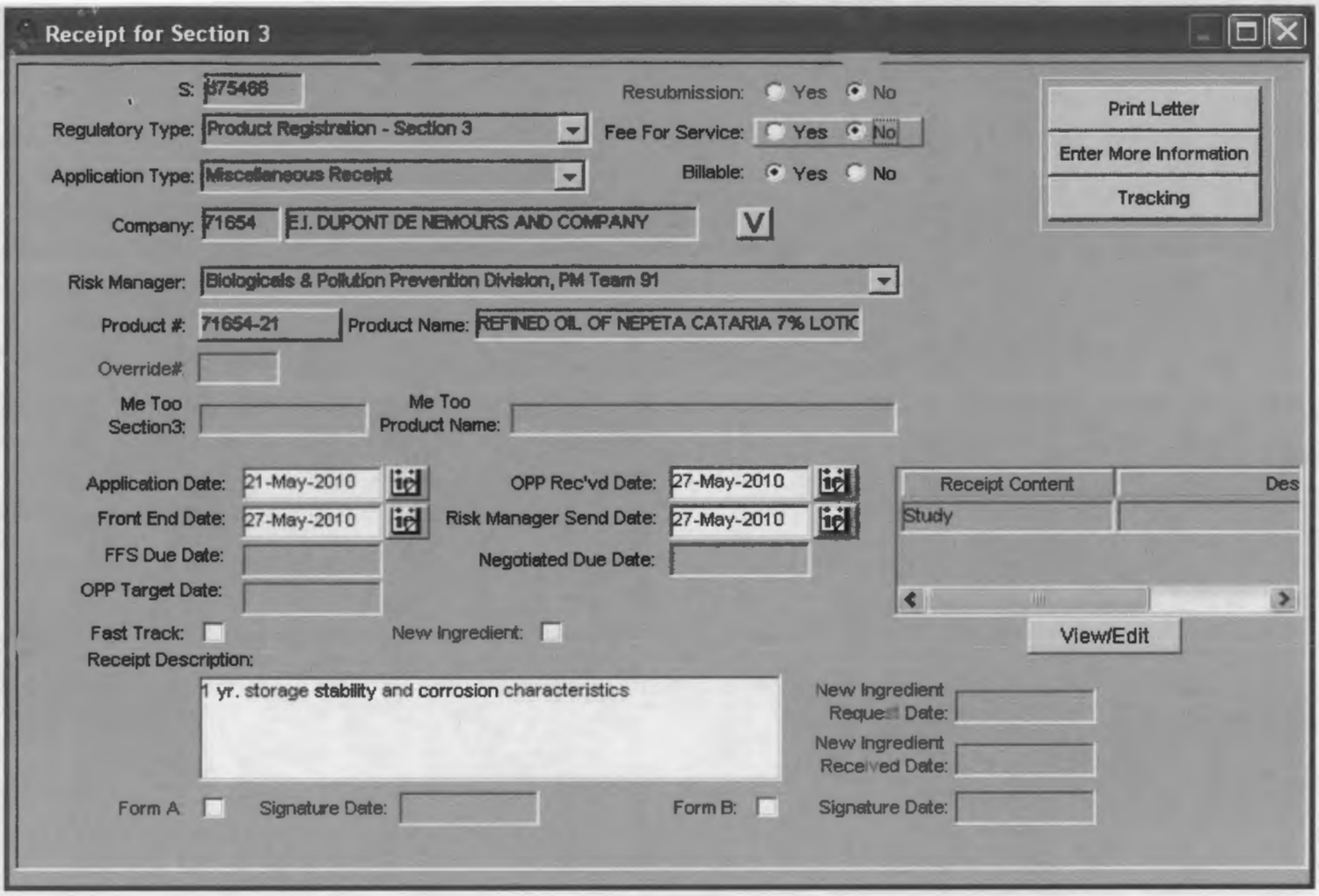
STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled**: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis)
- (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Complete Outdoor protection (OPT)
- Guards the whole family (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) formula (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Contains (a) plant-based Active Ingredient, Refined Oil of Nepeta cataria (OPT)
- Plant based repellent Active Ingredient, Refined Oil of Nepeta cataria (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (OPT)
- Contains plant extracts (OPT)
- Plant based ingredient (-do not settle for less efficacy) (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- For playing and relaxing outdoors (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)

- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)


Receipt for Section 3
S: 475466
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Miscellaneous Receipt
Billable: Yes No
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 71654-21
Product Name: REFINED OIL OF NEPETA CATARIA 7% LOTIC
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 21-May-2010
OPP Rec'vd Date: 27-May-2010
Front End Date: 27-May-2010
Risk Manager Send Date: 27-May-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
1 yr. storage stability and corrosion characteristics
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Decision #: 434657
DP #: (378694)
NON PRIA
Parent DP #:
Submission #: 875466

DATA PACKAGE BEAN SHEET

Date: 07-Jun-2010

* * * Registration Information * * *

Registration: 71654-21 - REFINED OIL OF NEPETA CATARIA 7% LOTION

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: Menyon Adams MADAMS07

Sent Date: 27-May-2010 Calculated Due Date: 14-Sep-2010 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 004801, Nepeta cataria oils(7%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 07-Jun-2010 Due Back:

DP Ingredient: 004801, Nepeta cataria oils

DP Title:

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	BPPD / BPB	07-Jun-2010		Last Possible Science Due Date: 06-Jul-2010
Team Name:	RM 91	07-Jun-2010		Science Due Date:
Reviewer Name:	Jones, Russell	07-Jun-2010		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Attention Russ,
Please review the storage and stability submission.
Thanks

Due Date August 16, 2010

48106201	Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p.	830.6320/Corrosion characteristics
48106200	E.I. du Pont de Nemours and Company (2010) Submission of Product Chemistry Data in Support of the Registrations of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, Refined Oil of Nepeta cataria 7% Lotion, Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid. Transmittal of 1 Study.	
48106201	Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p.	830.6317/Storage stability

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:	Date of Issuance:
71654-21	JUL 2 9 2009

Term of Issuance: Conditional

NOTICE OF PESTICIDE:

_____ Registration ____ Re-registration
(under FIFRA, as amended)

Name of Pesticide Product:

Refined Oil of *Nepeta cataria* 15% Lotion

Name and Address of Registrant (include ZIP Code):

DUPONT CHEMICAL SOLUTION ENTERPRISE
P.O. BOX 80402
WIL MINGTON, DE 19880-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c) (7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.

2. Submit a data package for the Guideline Study: OPPTS 830.6317 (Storage Stability), within 12 months from the date of issuance of this registration notice.

3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-21.

4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:
W. Michael McDavit

Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division

Date: 7-29-09

CONCURRENCES								
SYMBOL		7511P	7511P			7511P		
SURNAME			COLE			Hollis		
DATE			7/28/09			7/28/09		

EPA Form 8570-6

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

Refined Oil of *Nepeta cataria* 7% Lotion

Insect Repellent Lotion
Repels Mosquitoes and Black Flies

ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*.....	7.0%
Other Ingredients	93.0%
Total	100.0%

EPA Reg. No. 71654 – 23 [EG] EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

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